

Tomografia de Coerência Óptica

Dossiê de valor (COSAÚDE)

Domínio clínico

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Domínio clínico

Dossiê de valor da Tomografia de Coerência Óptica para avaliação de doença arterial coronariana e Intervenção Coronariana Percutânea.

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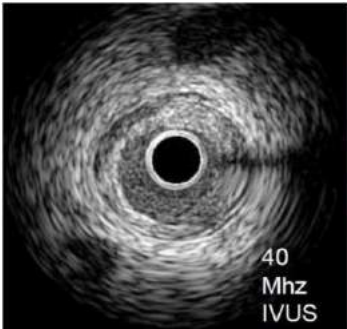

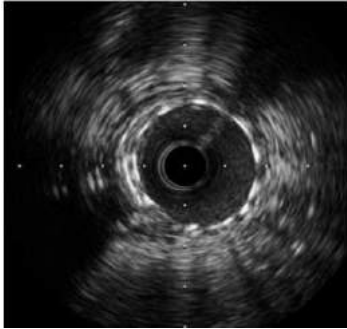
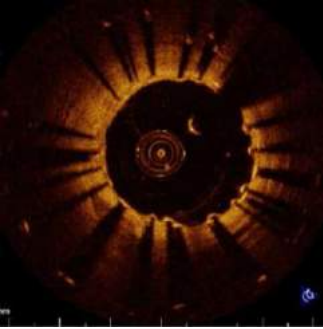
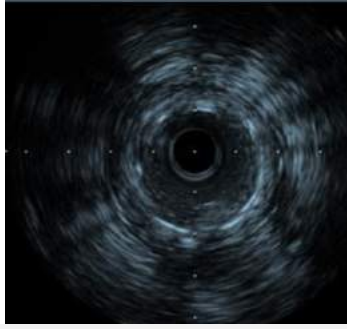
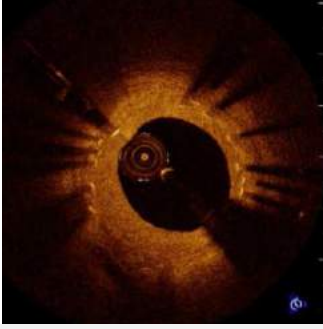
LISTA DE ABREVIATURAS E SIGLAS

ACE	Análise de custo-efetividade
AIO	Análise de impacto orçamentário
ANVISA	Agência Nacional de Vigilância Sanitária
ATS	Avaliação de tecnologias em saúde
CADTH	<i>Canadian Agency for Drugs and Technologies in Health</i>
DAC	Doença arterial coronariana
DCV	Doenças cardiovasculares
ECG	Eletrocardiograma
GRADE	<i>Grading of recommendations assessment, development and evaluation</i>
IAM CST/ SST	Infarto agudo do miocárdio com/ sem elevação do segmento ST
IQWiG	<i>Institute for Quality and Efficiency in Health Care;</i>
LDL	<i>Low density lipoprotein</i> (lipoproteína de baixa densidade)
MACE	<i>Major adverse cardiovascular events/</i> Eventos cardiovasculares maiores
NHS	<i>National Health Service</i>
NICE	<i>The National Institute for Health and Care Excellence</i>
PCI/ ICP	<i>Percutaneous coronary intervention/</i> Intervenção coronariana percutânea
OCT	<i>Optical coherence tomography/</i> Tomografia de coerência óptica
PBAC	<i>Pharmaceutical Benefits Advisory Committee</i>
RCEI	Relação de custo-efetividade incremental
SBU	<i>Swedish Council on Health Technology Assessment</i>
SCA	Síndrome coronariana aguda
SIGN	<i>Scottish Intercollegiate Guidelines Network</i>
SMC	<i>Scottish Medicine Consortium</i>
SSS	Sistema de saúde suplementar

RESUMO EXECUTIVO

Título	Dossiê de valor da tomografia de coerência óptica (OCT) para avaliação de doença arterial coronariana e intervenção coronariana percutânea.
Especialidade envolvida	Cardiologia.
Descrição da tecnologia	OCT é um método de obtenção de imagens formadas pelo uso de radiação infravermelha.
Mecanismo de ação	OCT utiliza cateteres de imagem que emitem luz com espectro próximo do infravermelho para produzir imagens de alta resolução em tempo real. As frequências e larguras de banda com espectro próximo do infravermelho usadas neste sistema resultam em uma resolução de imagem superior à das imagens médicas obtidas com técnicas padrão.

Comparativo de Imagens

	IVUS	OCT
Dissecção		
Overlapping		
Reestenose intra-stent		

Justificativa	OCT é uma técnica de imagem que otimiza o planejamento da intervenção coronariana, de forma a agregar à angiografia coronariana (padrão) detalhes sobre o local onde o procedimento será realizado. Dessa forma, o OCT proporciona (1) proporciona o implante de <i>stent</i> com acompanhamento diferenciado, uma vez que esta tecnologia possibilita a exata mensuração da extensão da lesão evitando a ocorrência de segmentos doentes sem tratamento; (2) permite a diferenciação da composição da placa de ateroma; (3) permite a identificação de possíveis intercorrências relacionadas ao implante do <i>stent</i>
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	durante o procedimento, tais como, mal posicionamento do <i>stent</i> e dissecação de bordos de <i>stent</i> ; (4) possibilita a correção imediata das intercorrências evitando eventos futuros, tais como, reestenose e trombose de <i>stent</i> .
População-alvo	Pacientes portadores de doença arterial coronariana submetidos a intervenção coronariana percutânea
Descrição da evidência científica clínica	Foram identificadas 3 revisões sistemáticas seguidas de metanálises e 16 estudos primários não contemplados pelas revisões. Para acurácia, estudos sugerem superioridade de OCT com relação à angiografia e similaridade ou superioridade em relação à IVUS a depender da avaliação realizada. Com relação a desfechos primordiais, Buccheri et al. identificaram que OCT é superior à angiografia com redução de 31% em eventos cardiovasculares maiores (MACE) e de 69% na mortalidade por causas cardiovasculares. Metanálises atualizadas conduzidas por autores do presente dossiê corroboram resultados identificados por Buccheri et al., sendo evidenciado maior benefício de OCT comparado à angiografia apenas no contexto de estudos de vida real mais próximas à realidade de incorporação.
Qualidade da evidência (comparação com angiografia coronariana - padrão)	MACE – Moderada; Recorrência de IAM – Baixa; Mortalidade por todas as causas – Baixa; Mortalidade por causas cardiovascular – Baixa.
Descrição das avaliações econômicas	<p><i>Análise de custo-efetividade</i></p> <p>O uso de OCT resulta em aumento nos anos de vida ganhos. A análise de custo efetividade mostrou que o uso de OCT, em comparação ao IVUS, proporcionou aos indivíduos um aumento de 0,4 anos de vida sem lesão e um aumento de 0,87 anos de vida total, para um incremento de R\$ 5.142. Em comparação à angiografia isolada, há aumento de 1,3 anos de vida sem lesão e 2,2 anos de vida totais, para um incremento de R\$ 13 mil. .</p> <p>Apesar de não haver um limiar estabelecido no Brasil, a magnitude dos resultados apresentados aponta para tecnologias mais custo-efetivas, usando como base o custo total de tratamento de pacientes que sofrem infarto do miocárdio e no valor anual arrecadado por esse perfil de pacientes durante um ano por planos de saúde.</p> <p><i>Análise de impacto orçamentário</i></p> <p>Embora haja um incremento de custos com a incorporação de OCT no sistema de saúde, o mesmo sofre diminuição quando os gastos totais do tratamento do paciente com DAC submetido à ICP são considerados. O custo incremental com a incorporação de OCT chega a cerca de R\$330 mil no quinto ano de análise.</p> <p>Embora não haja diferença estatística entre OCT e IVUS com relação aos desfechos clínicos, os valores médios para os mesmos favorecem OCT. Além disso, os intervalos de confiança referentes a esses desfechos e que foram utilizados na análise de sensibilidade da avaliação econômica apresentam maior frequência de valores que favorecem OCT. Por essa razão foi observado ganho de anos de vida com a utilização de OCT.</p>
Recomendação	Recomendado para a avaliação da lesão arterial coronariana (DAC) com características complexas e para guiar procedimento de revascularização percutânea (ICP).

IAM – Infarto agudo do miocárdio; RCEI – Razão de custo-efetividade incremental; ICP - intervenção coronariana percutânea; DAC - doença arterial coronariana.

1 DESCRIÇÃO CLÍNICA

Doença arterial coronariana (DAC) é uma das principais causas de angina e infarto agudo do miocárdio (IAM) no Brasil e no mundo. O diagnóstico e tratamento de IAM associado à DAC guiado por OCT proporcionam melhor colocação de *stent* e um acompanhamento médico diferenciado, uma vez que esta tecnologia permite o reconhecimento do tamanho da lesão, a composição da placa aterosclerótica, além de identificar problemas relacionados à colocação do *stent*. A relevância clínica e econômica de OCT é investigada neste dossiê de valor.

1.1. Patogênese e classificações

A doença arterial coronariana (DAC) é uma patologia causada por lesões provocadas ao endotélio vascular, caracterizada por um quadro inflamatório crônico de origem multifatorial. O surgimento de DAC ocorre de forma lenta e assintomática, e pode agravar e causar complicações agudas como, por exemplo, o infarto agudo do miocárdio (IAM).¹

Os danos endoteliais aumentam a permeabilidade vascular às lipoproteínas, que acabam se depositando na camada subendotelial, além de liberar moléculas de adesão leucocitária. O conjunto de partículas de lipoproteína de baixa densidade (*low density lipoprotein* – LDL) e de linfócitos e monócitos, posteriormente diferenciados em macrófagos, dão início ao processo de aterosclerose. A progressão da placa de aterosclerose se dá pela liberação de citocinas inflamatórias e enzimas capazes de produzir matriz extracelular.¹

A placa aterosclerótica pode ser considerada estável quando apresenta baixa atividade inflamatória e uma capa fibrosa espessa, e instável quando sua atividade inflamatória é intensa e há risco de ruptura da capa fibrosa. O rompimento dessa camada de proteção libera no interior do vaso um conteúdo altamente trombogênico, que é responsável pelo processo de aterotrombose e pelos eventos agudos resultantes da DAC.¹

A avaliação de um paciente com DAC é baseada nos sintomas relatados pelo paciente e nos achados clínicos e laboratoriais de exames diagnósticos. Quando há queixa de “dor no peito” as características relatadas pelo paciente são fundamentais para definir se trata-se de um tipo de dor

de origem cardíaca, caso contrário este sintoma pode ser apenas um fator de confusão. A história natural desta doença apresenta como principal complicação a Síndrome Coronariana Aguda (SCA), uma instabilidade isquêmica do miocárdio, que pode ser dividida em três classes conforme a gravidade e a necessidade de atendimento especializado de alta complexidade. As três classes são:²

- Angina instável (AI): dor de origem cardíaca, que não é atenuada com repouso ou nitratos, combinada com eletrocardiograma (ECG) sem sinais de isquemia e sem aumento dos níveis plasmáticos de enzimas cardíacas

- Infarto agudo do miocárdio sem elevação do segmento ST (IAM SST): dor de origem cardíaca, combinada com ECG sem sinais de isquemia e com aumento dos níveis plasmáticos de enzimas cardíacas

- Infarto agudo do miocárdio com elevação do segmento ST (IAM CST): dor de origem cardíaca, combinada com ECG com sinais de isquemia aguda e aumento dos níveis plasmáticos de enzimas cardíacas.

A classificação de pacientes que apresentam SCA é fundamental para direcionar a escolha de métodos de diagnóstico complementar ou intervenções terapêuticas imediatas.

1.2. Fatores de risco

São considerados fatores de risco para DAC: hipercolesterolemia, hipertensão, tabagismo, diabetes e história familiar de DAC precoce. Existem outros fatores que, apesar de não terem relação comprovada com o risco de DAC, são sinais de alerta para doenças cardiovasculares, como dislipidemia, sedentarismo, circunferência abdominal aumentada, hábitos alimentares não saudáveis.¹

Um estudo prospectivo conduzido na Finlândia com 14786 pessoas, mostrou que tabagismo aumenta o risco relativo em 1,77 e 2,14 em homens e mulheres respectivamente; diabetes aumenta o risco relativo em 2,0 e 2,29 em homens e mulheres respectivamente; o nível de colesterol aumenta em 1,34 e 1,21 (a cada 0,1mmol/L) em homens e mulheres, respectivamente,, e pressão arterial aumenta o risco relativo em 1,11 (a cada 10 mm Hg) para ambos os sexos.³

1.3. Epidemiologia

Desde a década de 60 a incidência e a prevalência de doenças crônicas não transmissíveis, como as doenças cardiovasculares (DCV), tem aumentado constantemente. Este fato é a consequência de um estilo de vida globalizado, urbanizado, com maior consumo de alimentos calóricos e redução de atividades físicas. O número de pessoas com DCV é acompanhado do aumento no número de pessoas com sobrepeso e obesas, e com o elevado consumo de tabaco.^{4,5}

A incidência de DAC na Finlândia é de 786 e 256 a cada 100.000 pessoas/ano em homens e mulheres, respectivamente.³ Na população dos Estados Unidos da América, a prevalência de DAC em pessoas maiores de 20 anos de idade, em 2008 era de 16 milhões (7,3%), e metade delas, 8,1 milhões (3,7%) tiveram pelo menos um IAM. E esses números aumentam conforme a faixa etária analisada.⁶

No Brasil, doenças cardiovasculares são responsáveis por cerca de 32% de todas as mortes, sendo que a DAC é a segunda causa de morte cardiovascular, embora em alguns estados como São Paulo a DAC ocupe o primeiro lugar na causa de mortes cardiovasculares. Em indivíduos com idade superior a 40 anos, a prevalência de DAC é estimada entre 5 a 8%^{7,8}.

1.4. Impacto clínico

Segundo a Organização Mundial da Saúde, DAC é a principal causa de morte no mundo, representando mais de 1 milhão de óbitos/ano em indivíduos entre 15 a 59 anos, e quase 6 milhões de mortes em maiores de 60 anos. Em outras palavras, quase 3,5 milhões e 4 milhões de mulheres e homens, respectivamente, morrem anualmente por DAC.⁹ Apesar da relevância clínico-epidemiológica da DAC, alguns países como Dinamarca (-48%), Suécia (-40%) e Luxemburgo (-30%), inclusive EUA (-30%) têm reduzido o número de pacientes que vão a óbito, especialmente pelo controle de fatores de risco modificáveis como tabaco, intervenções precoces e acuradas em síndromes agudas e uso de medicamentos que reduzem o risco de eventos cardiovasculares.¹⁰

Sabe-se que DCV têm ocupado o primeiro lugar no ranking de causas de morte no Brasil,⁵ ultrapassando as taxas de mortes por causas externas e neoplasias malignas. Em 2011, dentre todos os diagnósticos de DCV, DAC é a principal causa de morte, sendo responsável por 384 mil mortes, 31%, das mortes por DCV, mais do que acidentes cerebrovasculares (30%).⁵ O IAM é a principal causa de morte em pacientes com DAC e representa cerca de 80% dos óbitos registrados no país.⁷

1.5. Impacto humanístico

As consequências clínicas da DAC, como IAM e insuficiência cardíaca, são determinantes para a percepção de qualidade de vida do paciente. Indivíduos com DAC possuem qualidade de vida reduzida (média do domínio físico 53 ± 19 , em escala de 0 a 100), demonstrada por instrumentos validados como WHOQOL-BREF, da Organização Mundial da Saúde e SF-36 (média do domínio físico 59 ± 27 , *short form* 36, escala de 0 a 100). Outras pesquisas sobre qualidade de vida publicadas no Brasil, anos depois, vieram a corroborar com escores baixos em SF-36 em população semelhante, encontrando uma pontuação média menor no domínio físico ($\sim 40 \pm 38$), sugerindo agravos no estado de saúde percebido pelos pacientes com essa condição clínica.¹¹

Cruz et al. (2009) demonstraram que há correlação inversa entre escores reduzidos de qualidade de vida pelo WHOQOL-BREF, SF-36 (*short form* 36, todos os domínios) e depressão (pelo questionário BDI, *Beck Depression Inventory*). Ou seja, pacientes com DAC possuem menor qualidade de vida, o que por sua vez, está associado a piores escores de depressão ($r = -0,61$ e $p < 0,01$).

1.6. Impacto econômico

Devido à alta prevalência de DAC no Brasil, o consumo de recursos destinados ao tratamento e à reabilitação de pacientes é elevado. Em 2011, a estimativa de custo direto associado a IAM, no âmbito do SUS, foi de mais de 500 milhões de reais.¹² Em termos gerais, DCV tem o potencial de consumir 0,7% do Produto Interno Bruto no Brasil.¹³

Poucos estudos vieram a investigar especificamente sobre o impacto econômico da DAC, porém sendo essa uma das principais causa de DCV e etiologia de diversas complicações cardiovasculares maiores (ex.: IAM), o estudo de Azambuja (2008) estimou que o gasto total do sistema de saúde brasileiro com DCV foi de R\$ 11.229.124.084, sendo que cerca da metade desse custo é referente ao sistema suplementar de saúde¹⁴

O impacto econômico de eventos cardiovasculares maiores em perda de produtividade e custos indiretos também é marcante. Estima-se que uma pessoa com alto risco cardiovascular possua uma diferença de -24h menos de trabalho em comparação com uma pessoa sem DCV, representando

uma perda de produtividade média de –683 dólares/mês. Já uma pessoa que tenha que ser submetida a um procedimento clínico para tratar a DCV representa uma perda de produtividade de –1119 dólares/mês.¹⁵

1.7. Conduta preconizada

Pacientes portadores de DAC necessitam de exames de imagem a fim de investigar as características das placas de aterosclerose existentes e guiar a escolha do tratamento. O método considerado padrão-ouro para esta investigação é a angiografia de coronárias, inclusive durante a realização de uma angioplastia.¹⁶

Durante as últimas décadas surgiram novas tecnologias de imagem que possibilitaram análises mais detalhadas de lesões coronarianas. Tratam-se de técnicas de imagem intracoronária como o ultrassom intravascular (IVUS) e a tomografia de coerência óptica (OCT).

Em linhas gerais, ao se comparar as três modalidades acima mencionadas, angiografia de coronárias é a técnica utilizada desde a década de 70, sugerindo experiência de mais de 40 anos na cardiologia intervencionista, com reconhecido papel na identificação de lesões arteriais coronarianas.¹⁷ Com a evolução tecnológica na área, técnicas mais avançadas e acuradas de imagem, como IVUS e OCT, fossem inseridas nesta especialidade. IVUS permite visualização direta da parede arterial e da placa aterosclerótica, podendo detectar remodelação da placa com maior acurácia que a angiografia, além de alterações na severidade do ateroma.^{18,19} Já o OCT agrega benefícios adicionais em relação ao ultrassom intravascular pois permite uma resolução de imagem superior à IVUS, particularmente em relação à avaliação do posicionamento do *stent* no lúmen arterial, identificando complicações como mal posicionamento e dissecção de borda de *stent*²⁰, entre outras.

A importância de OCT pode ser vista no estudo ILUMIEN-I 467 em que estenoses foram tratadas em 418 pacientes portadores de angina estável, instável ou IAM SST. Ao final de 12 meses, as taxas de morte cardíaca (1,2% vs. 4,5%; $p = 0,01$), de morte cardíaca ou IAM (6,6% vs. 13%; $p = 0,006$), e do desfecho combinado de morte cardíaca, IAM e novas revascularizações (9,6% vs. 14,8%; $p = 0,044$) foram significativamente menores no grupo submetido a intervenção coronariana percutânea (ICP) guiada por tomografia de coerência óptica (*optical coherence tomography* – OCT). Após ajustes estatísticos, por análise multivariada e escores de propensão, a

ICP guiada por OCT permaneceu associada a risco significativamente menor de morte cardíaca ou IM (OR = 0,49; IC 95% = 0,25-0,96; p = 0,037).²¹

1.8. Necessidades não atendidas



As técnicas de imagem como IVUS e OCT permitem um melhor planejamento da intervenção coronariana, de forma a agregar à angiografia de coronárias detalhes sobre o local onde o procedimento será realizado. Pela sua capacidade de visualização, quando comparado ao IVUS, o OCT proporciona melhor colocação de *stent* e um acompanhamento médico diferenciado, uma vez que esta tecnologia permite o reconhecimento do tamanho da lesão, estudar a composição do ateroma, além de identificar problemas relacionados à colocação do *stent* (do posicionamento às complicações).²² O impacto e a relevância clínica e econômica dessas vantagens do OCT são investigadas neste dossiê.

2 DOMÍNIO ADMISSIBILIDADE

O dispositivo atende a requisitos técnicos e legais para que o uso em pacientes elegíveis seja seguro.

O Sistema de Imagem Ilumien Optis (modelo C408650) apresenta número de registro 10332340337 vigente até 24/11/2024 na ANVISA (Figura 1), assim como a importadora, St. Jude Medical Brasil Ltda apresenta autorização de funcionamento comum (nº: 1.03.323-4) e certificado de boas práticas de fabricação de produtos para saúde (Figura 2).

guro | <https://consultas.anvisa.gov.br/#/saude/25351385162201419/?numeroRegistro=10332340337>

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Detalhes do Produto			
Nome da Empresa	ST. JUDE MEDICAL BRASIL LTDA.		
CNPJ	00.986.846/0001-42.	Autorização	1.03.323-4
Produto	SISTEMA DE IMAGEM ILUMIEN OPTIS		

Modelo Produto Médico	
C408650	

Nome Técnico	Tomógrafo de Coerência Óptica
Registro	10332340337
Processo	25351.385162/2014-19
Origem do Produto	<ul style="list-style-type: none">FABRICANTE: LIGHTLAB IMAGING, INC - ESTADOS UNIDOS DA AMÉRICA
Classificação de Risco	III - ALTO RISCO
Vencimento do Registro	24/11/2024

Figura 1. Registro do produto na ANVISA.

www.anvisa.gov.br/certificadoBoasPraticas/principal/RESULTADO.ASP

Ministério da Saúde

Certificado de Boas Práticas

Página 1 de 1

CNPJ	EMPRESA SOLICITANTE	EMPRESA CERTIFICADA	ENDEREÇO	PAÍS	TIPO DE CERTIFICAÇÃO	LINHAS DE PRODUÇÃO / FORMAS FARMACÊUTICAS	RESOLUÇÃO	DATA DA PUBLICAÇÃO	VALIDADE DO CERTIFICADO
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	ST. JUDE MEDICAL - CARDIOVASCULAR AND ABLATION TECHNOLOGY DIVISION	5050 NATHAN LANE, PLYMOUTH, MINNESOTA, ESTADOS UNIDOS	ESTADOS UNIDOS DA AMÉRICA	CBPF	MATERIAIS	2524	08/09/2015	08/09/2017
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	ZONARE MEDICAL SYSTEMS, LLC	420 BERNARDO AVE., MOUNTAIN VIEW, CA 94043 - EUA	ESTADOS UNIDOS DA AMÉRICA	CBPF	INDEFERIMENTO	1661	06/06/2015	06/06/2017
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	OSYKA MEDICAL GMBH	ALBERT-EINSTEIN - STRASSE 3 - 12489 BERLIN - ALEMANHA	ALEMANHA	CBPF	EQUIPAMENTOS E MATERIAIS	1627	01/06/2015	01/06/2017
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	ST. JUDE MEDICAL GVA SARL		SUIÇA	CBPF	EQUIPAMENTOS (III)	930	30/03/2015	30/03/2017
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	LIGHTLAB IMAGING INC		ESTADOS UNIDOS DA AMÉRICA	CBPF	EQUIPAMENTOS (III) (IV)	929	30/03/2015	30/03/2017
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	ST. JUDE MEDICAL		ESTADOS UNIDOS DA AMÉRICA	CBPF	MATERIAIS	459	18/02/2015	18/02/2017
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	IRVINE BIOMEDICAL INC. A ST. JUDE MEDICAL COMPANY		ESTADOS UNIDOS DA AMÉRICA	CBPF	MATERIAIS	4951	29/12/2014	29/12/2016
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	ST. JUDE MEDICAL		ESTADOS UNIDOS DA AMÉRICA	CBPF	EQUIPAMENTOS E MATERIAIS	4677	22/12/2014	22/12/2016
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	ST. JUDE MEDICAL PUERTO RICO LLC		PORTO RICO	CBPF	EQUIPAMENTOS E MATERIAIS	3896	06/10/2014	06/10/2016
00.986.846/0001-42	ST. JUDE MEDICAL BRASIL LTDA.	GREATBATCH MEDICAL		ESTADOS UNIDOS DA AMÉRICA	CBPF	EQUIPAMENTOS	3097	18/08/2014	18/08/2016
00.986.846/0001-42	ST. JUDE MEDICAL	ADVANCED NEUROMODULATION		ESTADOS UNIDOS DA AMÉRICA	CBPF	EQUIPAMENTOS	2853	04/08/2014	04/08/2016

Figura 2. Certificado de Boas Práticas da empresa importadora. Disponível em: anvisa.gov.br.

Este equipamento médico-assistencial mede 1,43 x 4,71 x 6,83m (a x l x p), tem o peso igual a 95 kg, e pode ser conectado à rede elétrica de 100/120/220/240V, com uma potência de 50 – 60 Hz.

Não foi localizado nenhuma citação em documento oficial do Conselho Federal de Medicina que contraindicasse ou restringisse o uso de OCT na Cardiologia.

3 DOMÍNIO TÉCNICO

A OCT é uma modalidade de imagem que utiliza a tecnologia de fibra óptica, onde os raios infravermelhos usados neste sistema resultam em uma resolução de imagem superior à das imagens médicas obtidas com ultrassom (IVUS).

3.1. Descrição da tecnologia

A OCT é uma modalidade de imagem que utiliza a tecnologia de fibra óptica. O sistema ILUMIEN OPTIS utiliza cateteres de imagem que emitem luz com espectro próximo do infravermelho para produzir imagens de alta resolução em tempo real. As frequências e larguras de banda com espectro próximo do infravermelho usadas neste sistema resultam em uma resolução de imagem superior à das imagens médicas obtidas com ultrassom.

3.2. Indicação

O sistema de otimização PCI ILUMIEN™ OPTIS™ com cateter de imagem Dragonfly™ destina-se a:

- Realizar uma avaliação qualitativa e quantitativa da morfologia vascular das artérias coronárias;
- Servir como um complemento do procedimento angiográfico convencional, fornecendo uma imagem do lúmen e das estruturas da parede do vaso sanguíneo;
- Gerar imagens das artérias coronárias, sendo indicado para pacientes candidatos a um procedimento de intervenção transluminal;
- Adquirir sinais de radiofrequência do transdutor de pressão intracoronário distal e do transdutor de pressão aórtico proximal para determinar o parâmetro fisiológico, fluxo fracionado de reserva (FFR).

3.3. Acessórios

O sistema ILUMIEN OPTIS inclui os seguintes componentes, integrados em um carrinho móvel:

- Um motor responsável pela formação da imagem (OCT *imaging engine*);
- Software PCI *Optimization* instalado;
- Monitor do operador – LCD 17 polegadas de alta resolução;
- Monitor do médico – LCD 19 polegadas de alta resolução; Uma DOC (*Drive-motor and Optical Controller*);
- Um transformador de isolamento;
- Receptores para pressão aórtica e *PressureWire*;
- Um computador personalizado Ilumien Optis, um teclado e um mouse;
- Um cabo de alimentação;
- Console móvel integrado;
- Ferramentas acessórias;
- Manual do usuário.

3.4. Instruções de uso

3.4.1. Seleção do paciente

▪ Precauções e contraindicações

A utilização do sistema ILUMIEN OPTIS da St. Jude Medical é contraindicada nas situações em que a introdução de qualquer tipo de cateter constituir uma ameaça à segurança do paciente.

As contraindicações incluem:

- Anomalias graves do sistema de coagulação;
- Bacteremia ou sépsis;
- Instabilidade hemodinâmica grave ou choque;
- Insuficiência renal aguda;
- Pacientes diagnosticados com espasmo das artérias coronárias;
- Pacientes que não tenham indicação para cirurgia de revascularização miocárdica;

- Pacientes que não tenham indicação para PTCA (angioplastia coronária transluminal percutânea);
- Oclusão total;
- Trombos de grandes dimensões.

3.4.2. Procedimento de uso

▪ Descrição

O procedimento de OCT pode ser realizado por um ou dois operadores. Quando realizado por dois operadores, um operador deverá estar em assepsia e o outro operador sem assepsia. Todas as etapas que exigem contato com o cateter de imagem Dragonfly ou com o exterior da DOC devem ser realizadas pelo operador em assepsia. Todas as etapas executadas no interior da cobertura estéril da DOC ou em contato direto com o sistema ILUMIEN OPTIS devem ser realizadas pelo operador sem assepsia. Nos casos de realização do procedimento por um único operador, este deverá estar em assepsia e todas as etapas serão executadas via manejo da DOC.

▪ Materiais e equipamentos necessários

- Sistema ILUMIEN OPTIS
- Cateter de imagem C7 Dragonfly ou cateter de imagem Dragonfly Duo
- Cobertura estéril da DOC
- Seringa para irrigação de 3 ml
- Meio de contraste indicado para uso coronário, para irrigação e lavagem (reservar 15 ml para cada gravação planejada)
- Fio-guia de 0,014 polegadas (0,356 mm) (com dispositivo de torque, se necessário)
- Cateter-guia (6 Fr, diâmetro interno de 0,068 polegadas (1,727 mm) ou superior, sem orifícios laterais)
- Bainha introdutora (compatível com o cateter-guia)
- Adaptador/conector hemostático em Y
- Solução salina fisiológica, heparinizada, para a preparação do cateter hidrofílico.
- Bomba injetora para angiografia coronária ou seringa manual (com capacidade para injetar 4,0 ml/seg em um total de 14 ml em 3,5 segundos)

▪ **Visão geral do sistema de imagem OCT**

1. Position (Posicionar) - Posicione o cateter de imagem Dragonfly em relação à lesão alvo/stent.

2. Purge (Lavar) - Lave o sangue do lúmen do cateter, se presente, usando a seringa de 3 ml acoplada.

3. Puff (Injetar) - Injete uma pequena quantidade (~ 4 ml) de meio de contraste através do cateter-guia para avaliar a nitidez da imagem. Se a nitidez é marginal, verifique a orientação do cateter-guia e do vaso sanguíneo alvo.

4. Pullback (Retrair) - No modo Live View (Visualização ativa), selecione Enable (Ativar) para iniciar o processo de aquisição de imagem.

▪ **Modos de operação do OCT**

Durante a aquisição, o sistema opera em dois modos - Standby View (Visualização em espera) e Live View (Visualização ativa).

- Standby View (Visualização em espera) - A DOC não está rotacionando o cateter de imagem. A última imagem visualizada através da lente do cateter é apresentada na tela.
- Live View (Visualização ativa) - A DOC gira o cateter de imagem em baixa velocidade e transmite imagens para apresentação a partir da lente do cateter.

3.4.3. Monitoramento

▪ **Eventos adversos**

Os riscos envolvidos na obtenção de imagem vascular incluem os associados a todos os procedimentos de cateterismo. As seguintes complicações podem ocorrer como consequência da aquisição de imagem intravascular e podem necessitar de tratamento médico adicional, incluindo intervenção cirúrgica.

- Arritmias cardíacas;
- Dissecção, lesão ou perfuração arterial;
- Embolia;
- Enfarte agudo do miocárdio ou angina instável;

- Espasmo da artéria coronária;
- Formação de trombos;
- Morte;
- Reação alérgica ao meio de contraste.

4 DOMÍNIO CLÍNICO

Foi identificada evidência abrangente para desfechos relacionados à acurácia e desfechos primordiais na comparação de OCT com angiografia e IVUS. Para acurácia, coortes retrospectivas e estudos transversais sugerem superioridade de OCT com relação à angiografia e similaridade ou superioridade em relação a IVUS a depender da avaliação clínica considerada.

Com relação a desfechos primordiais, foi identificada superioridade de OCT com relação à angiografia com 31% de redução de eventos cardiovasculares maiores (MACE) e de 69% na mortalidade por causas cardiovasculares. Metanálises atualizadas conduzidas por autores do presente dossiê corroboram resultados identificados por Buccheri et al., sendo evidenciado maior benefício de OCT comparado à angiografia no contexto de estudos de vida real mais próximas à realidade de incorporação.

O presente documento segue as recomendações preconizadas nos documentos expedidos pelo Ministério da Saúde ²³⁻²⁶, os quais dispõem sobre as boas práticas de revisão sistemática, apresentação do documento principal e análise de qualidade de evidência e força de recomendação.

4.1 Pergunta

Com o intuito de tornar transparente e consistente, esclarece-se que este dossiê foi norteado pelo seguinte acrônimo PICOS:

Quadro 1. Pergunta norteadora do dossiê estruturada de acordo com o acrônimo PICOS.

P	Paciente (<i>patient</i>)	Aterosclerose, IAM, ICP, implante de <i>stent</i> , monitoramento a longo-prazo.
I	Intervenção (<i>intervention</i>)	OCT
C	Comparador (<i>comparator</i>)	Ultrassom intravascular (IVUS) Angiografia coronária (CA)
O	Desfecho (<i>outcome</i>)	Medidas angiográficas de lesão (acurácia, sensibilidade, especificidade) MACE Recorrência de IAM Mortalidade por todas as causas Mortalidade cardiovascular Revascularização de lesão-alvo Trombose de <i>stent</i>
S	Tipo de estudo (<i>study</i>)	Estudos transversais (acurácia), Ensaio clínico controlado, coorte comparativa, caso-controle, revisão sistemática e metanálise; Recomendações clínicas de agências de ATS e sociedades.

IAM: Infarto agudo do miocárdio, ICP: Intervenção coronariana percutânea, OCT: *Optical coherence tomography*/ Tomografia de coerência óptica, IVUS: *intravascular ultrasound*, CA: *coronary angiography*, MACE: *Major adverse cardiovascular events*/ Eventos cardiovasculares maiores.

Dessa forma, foram formuladas as questões chave relacionadas a seguir:

1. Qual é a acurácia, sensibilidade e especificidade de OCT comparado com angiografia coronária ou IVUS na avaliação de placa de aterosclerose?
2. Qual o impacto de OCT comparado com angiografia coronária ou IVUS para guiar ICP na incidência de MACE e recorrência de IAM?
3. Qual o impacto de OCT comparado com angiografia coronária ou IVUS para guiar ICP na mortalidade por todas as causas e causas CDV?
4. Qual o impacto de OCT comparado com angiografia coronária ou IVUS para guiar ICP na revascularização da lesão alvo e trombose de *stent*?

4.2 Critérios de elegibilidade

Um estudo foi elegível quando obedeceu ao acrônimo PICOS definido no item 4.1. Foram considerados critérios de exclusão quando os estudos eram voltados à comparação de *stents* e não

possuíam dados de OCT e os comparadores. Estudos que não foram redigidos em alfabeto romano também foram excluídos.

4.3 Busca de evidências

As bases de dados PubMed e Scopus foram utilizadas para a busca de estudos científicos. Salienta-se que Scopus e Embase compreendem o mesmo universo de publicações ²⁷, com o diferencial de que Scopus inclui literatura cinza, de forma que por estes motivos Embase não foi buscada. Busca manual de lista de referências incluídas também foi feita, sendo complementada por busca de recomendações clínicas de agências de ATS e sociedades (Apêndice I), a saber: *NICE – The National Institute for Health and Care Excellence; SMC – Scottish Medicine Consortium; CADTH – Canadian Agency for Drugs and Technologies in Health; PBAC – Pharmaceutical Benefits Advisory Committee; IQWiG – Institute for Quality and Efficiency in Health Care; SBU – Swedish Council on Health Technology Assessment; American Heart Association (AHA), American College of Cardiology (ACC), Society for Cardiovascular Angiography and Interventions (SCAI), European Society of Cardiology (ESC), European Association for Cardio-Thoracic Surgery (EACTS), Sociedade Brasileira de Cardiologia (SBC) e Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista (SBHCI).*

As estratégias de busca contemplaram descritores, palavras-chave e sinônimos para população, intervenção, comparadores e tipos de estudos, estruturadas segundo linguagem das respectivas bases de dados ou utilizando filtros validados, quando disponíveis (Apêndice II).

4.4 Extração de dados e avaliação das evidências

Dados foram extraídos em planilhas no Microsoft Office Excel® por um único revisor. Dados adicionais de materiais suplementares dos estudos identificados também foram extraídos. Como parte de um processo de validação, os extratos coletados dos estudos foram destacados e registrados em cópias PDF das publicações. As mesmas foram verificadas independentemente por um segundo revisor. Os documentos PDF estão disponíveis mediante solicitação.

A avaliação do risco de viés de diretrizes foi realizada pela ferramenta AGREE II adaptado ²⁸ e revisões sistemáticas seguidas de metanálises pela ferramenta *Risk of bias in systematic reviews (ROBIS)* ²⁹.

Avaliação da qualidade geral da evidência foi feita seguindo recomendações GRADE. De acordo com as Diretrizes Metodológicas do Ministério da Saúde ²⁵, qualidade de evidência diz respeito ao grau de confiança que se pode ter em uma determinada estimativa de efeito. Ou seja, se uma evidência é de alta qualidade é improvável que novas pesquisas produzam mudanças substanciais na estimativa de efeito. Por outro lado, se uma evidência é muito baixa, futuros estudos com delineamentos mais apropriados poderão confirmar ou refutar os efeitos observados.

4.5 Resultados das buscas

A revisão sistemática de revisões sistemáticas identificou 355 registros depois de remoção de duplicidades; 346 foram considerados irrelevantes durante a triagem e 5 foram excluídos após leitura dos textos na íntegra (Apêndice III). Nenhuma revisão sistemática foi identificada por busca manual. Os três registros representam revisões sistemáticas com metanálise (Tabela 1) publicadas entre 2015 e 2017. Duas revisões sistemáticas incluíram ensaios clínicos e observacionais, e uma revisão incluiu estudos de acurácia.

Com o objetivo de tornar este dossiê atualizado, foram buscados estudos primários publicados entre 2010 e 2018. A busca por estudos primários identificou 889 registros depois da remoção de duplicidades; 887 foram considerados irrelevantes durante a triagem (Apêndice IV). Foram incluídos 16 estudos, sendo 15 de acurácia e 1 para desfechos duros, não contemplados nas 3 revisões sistemáticas (Tabela 2).

Tabela 1. Características das revisões sistemáticas seguidas ou não de metanálises incluídas.

Estudo	Desenho	População	Alternativas comparadas	Desfechos	Tipos de estudos incluídos	N estudos (N participantes)*
Buccheri, 2017 ¹⁵	RS e RM	PCI	OCT ou IVUS vs CA	Mortalidade por todas as causas, MACE, Morte CV, IAM, RLA, TS	ECR e Observ.	31 (17882)
Kuku, 2017 ³¹	RS e MD	PCI	OCT vs IVUS ou CA	MACE, Morte CV, IAM, RLA, TS	ECR e Observ.	6 (1288)
D'Ascenzo, 2015 ³³	RS e MD	Estenose	OCT ou IVUS vs FFR	Acurácia, Sensibilidade, Especificidade	Estudos de acurácia	5 (224)

*número de estudos e participantes incluídos para os desfechos de interesse no presente dossiê. MACE: principais eventos cardiovasculares, CV: cardiovascular, RLA: revascularização da lesão alvo, TS: trombose do *stent*, FFR: reserva fracionada de fluxo, RS: revisão sistemática; MD: metanálise direta, MR: rede de metanálises, OCT: *Optical Coherence Tomography*, IVUS: *Intravascular Ultrasound*, IAM: infarto agudo do miocárdio.

Tabela 2. Características dos estudos primários incluídos.

Estudo	Desenho	População	N participantes (N homens)	Alternativas comparadas	Idade	Desfechos	Conclusão
Jones, 2018³²	Observacional	PCI	87.166 (64.592)	OCT, IVUS e CA	65.2	Mortalidade por todas as causas, MACE e IAM.	Uma diferença significativa na mortalidade foi observada entre pacientes que foram submetidos a PCI guiada por OCT (7,7%) em comparação com pacientes que foram submetidos a guia por IVUS (12,2%) ou angiografia apenas (15,7%; $p < 0,0001$).
Kume, 2005³³	Transversal (Ex vivo)	-	54 amostras (18 pacientes – 10 homens)	OCT, IVUS, histologia	72 ± 6	- Espessura da Camada Íntima-Média - Área luminal - Espessura da íntima	Correlação AL (OCT vs Hist): $y=0.99x+0.24$, $r=0.97$, $p<0.001$ Correlação AL (IVUS vs Hist): $y=0.94x+0.64$, $r=0.96$, $p<0.001$ Correlação ECMI (OCT vs Hist): $y=0.87x+0.08$, $r=0.95$, $p<0.001$, DM= -0.01 ± 0.07 mm; Correlação ECMI (IVUS vs Hist): $y=0.85x+0.11$, $r=0.88$, $p<0.001$, DM = -0.03 ± 0.10 mm Correlação EI (OCT vs Hist): $y=0.85x+0.06$, $r=0.98$, $p<0.001$ Não foi possível medir EI com IVUS

Rieber, 2006³⁴	Transversal (Ex vivo)	-	323 amostras (8 pacientes – 7 homens)	OCT vs IVUS vs histologia	72 ± 11	Sensibilidade e especificidade	<p>Sensibilidade e especificidade de OCT:</p> <ul style="list-style-type: none"> - 91/88% para tecido normal; - 64/88% para placa fibrosa; - 77/94% para placa lipídica - 67/97% para placa de cálcio <p>Sensibilidade e especificidade de IVUS:</p> <ul style="list-style-type: none"> - 55/79% para tecido normal; - 63/59% para placa fibrosa; - 10/96% para placa lipídica - 76/98% para placa de cálcio
Kume, 2006³⁵	Transversal (Ex vivo)	-	108 amostras (40 pacientes- 24 homens)	OCT vs IVUS vs histologia	74 ± 7	Sensibilidade e especificidade	<p>OCT apresentou maior sensibilidade para caracterizar placas lipídicas (85% vs 59%, p = 0,03).</p> <p>Sensibilidade e especificidade de OCT:</p> <ul style="list-style-type: none"> - 79/99% para placa fibrótica - 96/88% para placa de cálcio - 85/94% para placa lipídica <p>Sensibilidade e especificidade de IVUS:</p> <ul style="list-style-type: none"> - 88/86% para placa fibrótica - 98/96% para placa de cálcio - 59/97% para placa lipídica
Kawasaki, 2006³⁶	Transversal (Ex vivo)	Doença cardiovascular sintomática	128 amostras (17 pacientes)	OCT vs IVUS vs histologia	-	Sensibilidade e especificidade	<p>Sensibilidade e especificidade de OCT:</p> <ul style="list-style-type: none"> - 100/100% para calcificação – VPP: 100; VPN: 100 - 98/94% para fibrose – VVP: 98; VPN: 94 - 95/98% para placas lipídicas – VPP: 90; VPN: 99 <p>Sensibilidade e especificidade de IVUS:</p> <ul style="list-style-type: none"> - 100/99% para calcificação – VPP: 88; VPN: 100

							- 93/61% para fibrose – VPP: 87; VPN: 74 - 67/95% para placas lipídicas – VPP: 67; VPN: 95
Kubo, 2007 ³⁷	Transversal	IAM	30 (19)	OCT, IVUS, AC	69 ± 11	Rompimento da capa fibrosa Erosão da capa fibrosa Trombo	Detecção de rompimento da capa fibrosa: 73%, 47% e 40% com OCT, AC e IVUS. Diferença significativa entre OCT e AC (p = 0,035) e OCT e IVUS (p = 0,009). Detecção da erosão da capa fibrosa: 23%, 3%, e 0% com OCT, AC e IVUS. Diferença significativa entre OCT e AC (p = 0,026) e OCT e IVUS (p = 0,005). Detecção de trombo: 100%, 100% e 33% com OCT, IVUS e AC. Apenas OCT conseguiu estimar a espessura da capa fibrosa 49 ± 21 µm
Kubo, 2011 ³⁸	Transversal	Angina estável	96 (72)	OCT vs VH-IVUS	69 ± 9	Acurácia de VH-IVUS para detecção de TCFA, em relação ao OCT	Sensibilidade: 89% Especificidade: 86% Valor preditivo positivo: 59% Valor preditivo negativo: 97%

Gonzalo, 2012³⁹	Transversal	1 ou mais estenoses coronarianas de gravidade intermediária	56 (47)	OCT vs IVUS	62 ± 11	Identificação de estenose coronariana	<p>Capacidade de diagnóstico do OCT foi moderada (ASC: 0,74; IC 95%: 0,61 a 0,84), com sensibilidade/especificidade de 82%/63% com um cut-off de 1,95 mm².</p> <p>Capacidade de diagnóstico de IVUS (ASC: 0,70; IC 95% 0,55 a 0,83) e IVUS (ASC: 0,63; IC 95% 0,47 a 0,77; p = 0,19).</p> <p>Sensibilidade/especificidade de IVUS foi de 67%/65% com um cut-off de 2,36 mm².</p> <p>Subgrupo de vasos de pequeno caliber (<3 mm): OCT tem melhor capacidade diagnóstica (ASC: 0,77; IC 95%: 0,60 a 0,89) vs IVUS (ASC: 0,63; IC 95%: 0,46 a 0,78) (p = 0,04).</p>
Takahashi, 2013⁴⁰	Transversal	Pacientes com angina estável e síndrome coronariana aguda que realizaram ICP	70 (49)	OCT vs IVUS	65,5 ± 9,9	Sensibilidade e especificidade para detectar placas lipídicas e TCFA identificado por OCT	<p>OCT -padrão</p> <p>Deteção de placas lipídicas por IVUS: cut-off de AN: 33% (ASC: 0,75; sensibilidade: 73,2%; especificidade: 67,3 %)</p> <p>Deteção de TCFA por IVUS: sensibilidade: 75%; especificidade: 71,6%; Valor preditivo positivo: 37,5%; Valor preditivo negativo: 92,6%; acurácia do diagnóstico: 72,2%</p>

Brown, 2015 ⁴¹	Transversal (Ex vivo)	-	258 amostras (10 pacientes - 71,4% homens)	OCT vs IVUS vs histologia	71,1 ± 11,8	Detecção de TCFA	<p>Detecção de qualquer ateroma</p> <p>Acurácia: 77,5% (IVUS) e 89% (OCT)</p> <p>Sensibilidade: 70,1% (IVUS) vs 82,1 (OCT)</p> <p>Especificidade: 81,2% (IVUS) vs 92,5% (OCT)</p> <p>Valor preditivo positivo: 65,3% (IVUS) vs 84,6% (OCT)</p> <p>Valor preditivo negativo: 84,4% (IVUS) vs 91,1% (OCT)</p> <p>Detecção de TCFA</p> <p>Acurácia: 76.5% por IVUS e 79% por OCT.</p> <p>Sensibilidade: 63,6% (IVUS) e 72,7% (OCT).</p> <p>Especificidade: 78,1% (IVUS) vs 79,8% (OCT)</p> <p>Valor preditivo positivo: 26,4% (IVUS) vs 95,9% (OCT)</p> <p>Valor preditivo negativo: 94,6% (IVUS) vs 95,9% (OCT).</p>
Alfonso, 2015 ⁴²	Transversal	Trombose de stent	15 (15)	OCT vs IVUS	64 ± 11	Medidas e posição de stent	<p>Stent mal posicionado pré ICP: 40% com IVUS vs 47% com OCT</p> <p>Pós ICP: 27% com IVUS vs 33% com OCT</p> <p>Detecção de trombo pré ICP: 100% vs 100% com OCT</p> <p>Detecção de trombo pós ICP: 80% vs 100% com OCT</p>
Sohn, 2015 ⁴⁸	Coorte retrospectiva	PCI e follow up (24 meses)	38 (26)	OCT e IVUS	59	Dados angiográficos, sensibilidade, especificidade	OCT identificou mais prolapso de tecido, mas não houve diferença em desfechos clínicos.

Toutouzas 2015⁴⁴	Transversal	Segmentos de artéria coronária nativa (principalmente) e stent	30	3D OCT, 3D IVUS e 3D AC	NR	Sensibilidade Especificidade	3D OCT foi altamente sensível e específico em identificar subsegmentos com baixo ESS (≤ 0.5 Pa) e alto ESS (> 0.5 Pa) usando 3D IVUS as padrão-ouro (sensibilidade = 0.80, especificidade = 0.80, valor preditivo positivo = 0.80, valor preditivo negativo = 0.80). Além disso, 3D OCT mostrou alta sensibilidade e especificidade em identificar subsegmentos com baixo ESS (≤ 0.5 Pa) e alto ESS (> 0.5 Pa) comparado à AC (sensibilidade = 0,81, especificidade = 0,80, valor preditivo positivo = 0,81, valor preditivo negativo = 0,80). 3D OCT exibiu uma excelente concordância inter e intra-observador.
Wang, 2017⁵²	Coorte retrospectiva	AE	440 (363)	OCT, IVUS e CA	66	Composição da placa de aterosclerose	OCT e IVUS detectam áreas calcificadas invisíveis à CA, que não influenciam na dilatação do stent.
Zeng 2017⁴⁶	Transversal	PCI	15 (9)	OCT e IVUS	59,1 \pm 7,2	Sensibilidade Especificidade	Detenção de calcificação: Baseline e 5 anos – OCT, Sensibilidade = 70%, Especificidade = 100%, IVUS (escala cinza), Sensibilidade = 95,7%, Especificidade = 100%, IVUS (histologia virtual), Sensibilidade = 100%, Especificidade = 70,5%.
Usui 2018⁴⁷	Transversal	Estenose coronariana	186 (155)	OCT e IVUS	66,1 \pm 9,7	Sensibilidade Especificidade Acurácia	Presença de isquemia (FFR < 0.75): IVUS – sensibilidade = 71,8%, especificidade = 47%, acurácia = 55,7%; OCT –

sensibilidade = 69,0%;
especificidade = 68,9% e
acurácia = 69,9%

AC: Angiografia coronária; ACT: angiografia por tomografia computadorizada; AE: Angina estável; ASC: Área sob a curva; CA: Angiografia Coronária; ESS: endothelial shear stress; ICP/PCI: Intervenção Coronariana Percutânea; IVUS: *Ultrassom Intravascular*; NA: Área necrótica; NSTEMI: infarto do miocárdio sem supradesnívelamento do segmento ST; OCT: Tomografia de Coerência Óptica; TCFA – Fibroateroma de capa fina ; VH-IVUS: Virtual histology intravascular ultrasound.

As buscas por recomendações das agências de ATS para uso do OCT em ICP retornaram a avaliação do NICE (IPG 481, de 2014), que recomenda o uso da tecnologia sob circunstâncias em que os provedores de saúde informem os gestores locais e o sistema de auditoria em cardiologia quanto aos dados do paciente e os detalhes do procedimento.⁴⁸

Ainda com o intuito de obter as melhores recomendações acerca dos tratamentos de AOS foram realizadas buscas manuais de diretrizes clínicas, as quais retornaram documentos da *American Heart Association* (AHA), *American College of Cardiology* (ACC), *Society for Cardiovascular Angiography and Interventions* (SCAI), *European Society of Cardiology* (ESC), *European Association for Cardio-Thoracic Surgery* (EACTS), Sociedade Brasileira de Cardiologia (SBC) e Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista (SBHCI).

Em 2011, as diretrizes clínicas de ICP da ACC/AHA/SCAI ainda consideravam que o papel apropriado para a OCT na tomada de decisão clínica de rotina não era bem estabelecido⁴⁹. Em 2014 essas mesmas sociedades médicas publicaram novas diretrizes clínicas sobre o manejo de pacientes com Síndromes Coronarianas Agudas (SCA) sem elevação de ST, considerando a tomografia de coerência óptica (OCT) como opção para avaliar a extensão da aterosclerose e excluir lesões obstrutivas em pacientes com possíveis SCA e coronárias angiograficamente normais ou não obstrutivas (<50% de estenose)⁵⁰.

As diretrizes sobre ICP da SBC e SCAI (2017)⁵¹ consideram que o OCT pode ser utilizada para estimar o significado funcional de lesões angiograficamente intermediárias (40-70%) em coronárias nativas, à exceção do Tronco de Coronária Esquerda e que pode ser utilizada para identificação de lesões culpadas no cenário das SCA, quando essa informação não pode ser obtida pela avaliação clínica ou eletrocardiográfica; consideram que o OCT pode ser utilizada, em casos selecionados, para guiar e otimizar o implante de *stents* metálicos, recomendação corroborada por ESC e EACTS em diretrizes de 2014 sobre revascularização do miocárdio⁵²; também consideram que o OCT pode ser utilizada, em casos selecionados, para guiar e otimizar o implante de suportes vasculares biorreabsorvíveis; também consideram que o OCT pode ser utilizada para determinar o mecanismo de falência (reestenose e trombose de *stent*) de *stents* metálicos (corroborada por ESC e EACTS em 2014)⁵² e suportes vasculares biorreabsorvíveis, assim como a integridade estrutural dos suportes biorreabsorvíveis após o implante e a longo prazo.

4.5.1 Avaliação crítica dos registros selecionados

As revisões sistemáticas foram avaliadas pela ferramenta ROBIS, a qual é dividida em quatro domínios obrigatórios. O primeiro domínio, referente aos critérios de elegibilidade do estudo, apresentou baixo risco para a maioria das revisões. O segundo domínio, relacionado a identificação e seleção dos estudos, apresentou alto risco de viés para a maioria das revisões, devido a quantidade insuficiente base de dados de maior confiabilidade, ausência da estratégia de busca utilizada, restrição para idioma e data. O terceiro domínio, referente a coleta de dados e avaliação dos estudos, apresentou baixo risco de viés metade dos estudos e risco incerto para a outra metade, devido à ausência de avaliação de qualidade metodológica. O quarto domínio referente a síntese e achados apresentou baixo risco de viés para todas as revisões. Assim, o risco de viés global das revisões foi considerado alto ($n = 3$) (Tabela 3).

Tabela 3. Avaliação do risco de viés das revisões sistemáticas (ROBIS).

REVISÃO	FASE 2				FASE 3
	Critérios de elegibilidade do estudo	Identificação e seleção dos estudos	Coleta de dados e avaliação dos estudos	Síntese e achados	Risco de viés na revisão
Buccheri, 2017	😊	😞	😞	😊	😞
Kuku, 2017	😞	😞	😞	😊	😞
D'Ascenzo, 2015	😊	😞	😞	😊	😞
😊 = baixo risco; 😞 = alto risco; ? = risco incerto.					

As diretrizes clínicas foram submetidas à avaliação de qualidade AGREE (*Appraisal of Guidelines for Research & Evaluation*)⁵³, com o intuito de abordar a variabilidade na qualidade, avaliar o rigor metodológico e transparência no desenvolvimento destes materiais, sob o ponto de vista dos autores deste dossiê. Na Tabela 4 são apresentadas as avaliações das diretrizes de acordo com os padrões do instrumento, em que 23 parâmetros de qualidade são julgados numa escala de 1 a 7 (1 significa qualidade mais baixa e 7 significa qualidade mais alta possível). Os resultados apresentados na Figura 3 representam a proporção da coerência destas diretrizes com os domínios analisados, expressos em porcentagens. Na Figura 4 estão expressas as avaliações globais de

recomendação destas diretrizes, numa escala de 1 a 7 (1 significa qualidade mais baixa e 7 significa qualidade mais alta possível).

Tabela 4. Avaliação do risco de viés nas diretrizes (AGREE II adaptado).

		DIRETRIZES			
Domínio	Quesito	ACC/AHA/SCAI (2011) ⁴⁹	ACC/AHA/SCAI (2014) ⁵⁰	SBC/SCAI (2017) ⁵¹	ESC/EACTS (2014) ⁵²
Escopo e finalidade	1. O(s) objetivo(s) geral(is) da(s) diretriz(es) está(ão) especificamente descrito(s).	7	7	7	3
	2. A(s) questão(ões) de saúde coberta(s) pela diretriz está(ão) especificamente descrita(s).	7	7	4	5
	3. A população (pacientes, público etc.) a quem a diretriz se destina está especificamente descrita.	6	7	6	6
Envolvimento das partes interessadas	4. A equipe de desenvolvimento da diretriz inclui indivíduos de todos os grupos profissionais relevantes.	7	7	7	6
	5. Procurou-se conhecer as opiniões e preferências da população-alvo (pacientes, público etc.).	1	2	1	3
	6. Os usuários-alvo da diretriz estão claramente definidos.	7	7	4	5
Rigor do desenvolvimento	7. Foram utilizados métodos sistemáticos para a busca de evidências.	4	5	1	1
	8. Os critérios para a seleção de evidências estão claramente descritos.	3	7	3	2
	9. Os pontos fortes e limitações do corpo de evidências estão claramente descritos.	2	6	3	2
	10. Os métodos para a formulação das recomendações estão claramente descritos.	3	4	3	3
	11. Os benefícios, efeitos colaterais e riscos à saúde foram considerados na formulação das recomendações.	5	5	4	3

Clareza da apresentação	12. Existe uma relação explícita entre as recomendações e as evidências que lhe dão suporte.	6	7	6	6
	13. A diretriz foi revisada externamente por experts antes da sua publicação.	4	7	1	4
	14. Um procedimento para atualização da diretriz está disponível.	3	7	1	3
	15. As recomendações são específicas e sem ambiguidade.	5	7	5	5
	16. As diferentes opções de abordagem da condição ou problema de saúde estão claramente apresentadas.	6	7	6	5
	17. As recomendações-chave são facilmente identificadas.	7	7	6	7
	18. A diretriz descreve os fatores facilitadores e as barreiras para a sua aplicação.	5	6	1	3
Aplicabilidade	19. A diretriz traz aconselhamento e/ou ferramentas sobre como as recomendações podem ser colocadas em prática.	5	5	1	5
	20. Foram consideradas as potenciais implicações quanto aos recursos decorrentes da aplicação das recomendações.	2	2	2	2
	21. A diretriz apresenta critérios para o seu monitoramento e/ou auditoria.	4	4	2	4
Independência editorial	22. O parecer do órgão financiador não exerceu influência sobre o conteúdo da diretriz.	4	6	4	7
	23. Foram registrados e abordados os conflitos de interesse dos membros da equipe que desenvolveram a diretriz.	7	7	7	7

S: Sim, N: Não, SR: Sem resposta.

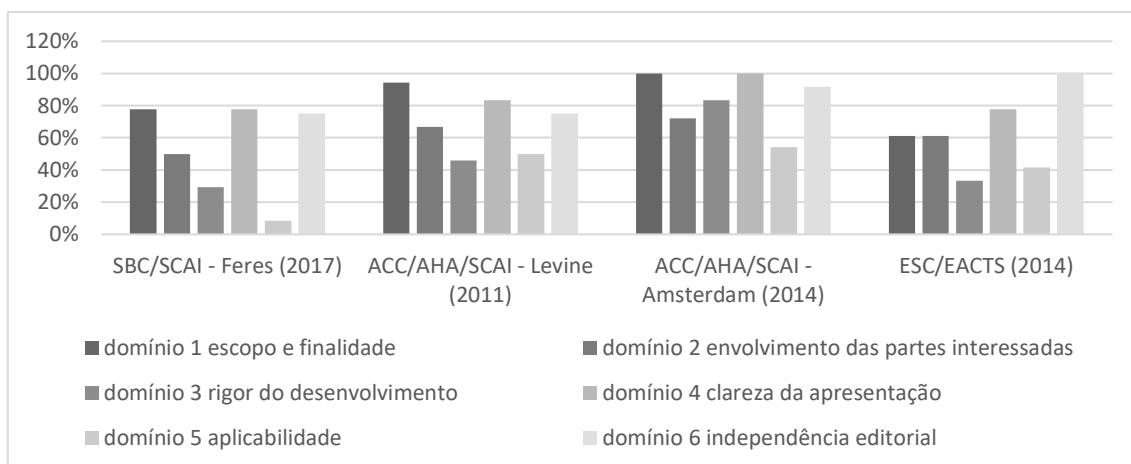


Figura 3: Proporção de coerência das diretrizes analisadas

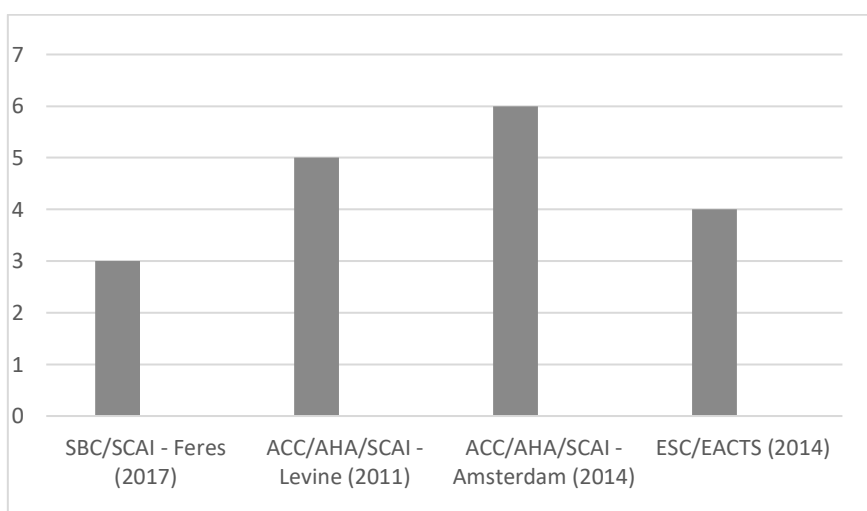


Figura 4: Avaliação global de recomendações das diretrizes

Com relação à qualidade geral da evidência, consideramos a metanálise em rede conduzida por Bucchieri et al. tendo em vista a maior abrangência de estudos e desfechos primordiais. A revisão considerou pacientes em diferentes condições clínicas como DAC, AE, AI, AIMSST e IAMCST. No entanto, para todos os desfechos houve rebaixamento da qualidade tendo em vista limitações metodológicas dos estudos incluídos e para a maioria rebaixamento por ausência de diferença com significância estatística (Tabela 5). Como poderá ser visto a seguir, os autores do presente dossiê conduziram atualização da metanálise conduzida por Bucchieri et al. (2017) tendo em vista a publicação de um estudo observacional de elevado tamanho amostral em 2018. No entanto, mesmo após adição deste estudo, tanto conclusões quanto confiança na evidência não seria alterada.

Tabela 5. Avaliação da qualidade da evidência para cada desfecho (GRADE).

Desfechos	Estudos (Participantes)	Resultado	Confiança na evidência
Comparação: OCT vs CA			
MACE	27 (16880)	0,69 (0,49; 0,98)	Moderada ¹
IAM	28 (15925)	0,80 (0,45; 1,40)	Baixa ^{1,2}
Mortalidade por todas as causas	23 (13656)	0,61 (0,31; 1,20)	Baixa ^{1,2}
Mortalidade por causas CDV	21 (13398)	0,31 (0,13; 0,67)	Moderada ¹
Comparação: OCT vs IVUS			
MACE	27 (16880)	0,87 (0,61; 1,30)	Baixa ^{1,2}
IAM	28 (15925)	1,10 (0,61; 2,10)	Baixa ^{1,2}
Mortalidade por todas as causas	23 (13656)	0,81 (0,41; 1,60)	Baixa ^{1,2}
Mortalidade por causas CDV	21 (13398)	0,66 (0,28; 1,50)	Baixa ^{1,2}

1: Confiança rebaixada por baixa qualidade metodológica dos estudos incluídos, 2: Confiança rebaixada por imprecisão.

IAM: Infarto agudo do miocárdio, OCT: *Optical coherence tomography*/ Tomografia de coerência óptica, IVUS: *intravascular ultrasound*, CA: *coronary angiography*, MACE: *Major adverse cardiovascular events*/ Eventos cardiovasculares maiores, CDV: cardiovasculares.

4.5.2 Síntese das evidências científicas

As evidências científicas são discutidas no âmbito de cada questão proposta inicialmente.

QUESTÃO 1. Qual é a acurácia, sensibilidade e especificidade de OCT comparado com angiografia coronária ou IVUS na avaliação da placa de aterosclerose?

Uma revisão sistemática com metanálise foi identificada para desfechos relativos à acurácia de OCT em pacientes com estenose. A revisão incluiu 15 estudos, sendo cinco (n = 224 pacientes) avaliando OCT e nove (n = 1532 pacientes) avaliando IVUS. O padrão-ouro para avaliação de estenoses coronária foi a reserva fracionada de fluxo. Os autores concluem que IVUS e OCT podem ser uma ajuda valiosa em contextos clínicos complexos, nos quais as medidas padrão têm limitações para estabelecer a estratégia de revascularização (Tabela 6).

Tabela 6. Sumário dos resultados obtidos por estudo conduzido por D’Ascenzo et al. 2015.

	OCT (IC 95%), I ²	IVUS (IC 95%), I ²
	Área luminal mínima	
Curva ROC	0,80 (0,74; 0,86)	0,78 (0,75; 0,81)
Sensibilidade	0,81 (0,74; 0,87), 40,2%	0,68 (0,65; 0,71), 72,3%
Especificidade	0,77 (0,71; 0,83), 34,7%	0,68 (0,66; 0,70), 86,1%
	Diâmetro luminal mínimo	
Curva ROC	0,85 (0,79; 0,91)	0,97 (0,93; 1,00)
Sensibilidade	0,81 (0,74; 0,87), 0%	NR
Especificidade	0,77 (0,68; 0,73), 0%	NR

OCT: Tomografia de Coerência Óptica; IVUS: Ultrassom Intravascular; Curva ROC: área sob a curva de característica de operação do receptor.

A avaliação do tamanho (gravidade) da lesão coronariana é fundamental para o impacto prático e clínico, escolha da intervenção e previsão do prognóstico. Nessa revisão sistemática observa-se que tanto OCT como IVUS apresentam acurácia moderada para detecção de lesões, embora OCT apresente melhores valores de sensibilidade e especificidade para a medida de área luminal mínima. Os autores discutem que o OCT tem o potencial de apresentar superioridade de acurácia diagnóstica em pequenos vasos.

Em lesões intermediárias, a OCT tem um benefício potencial como meio adjunto de avaliar a anatomia e composição de placas de gravidade ou morfologia incertas, e a detecção de características adversas que requerem intervenção adicional poderia reduzir significativamente o risco de morte e infarto do miocárdio.

Tendo em vista que a revisão foi conduzida em 2015, foram buscados estudos primários publicados entre 2015 e 2018, sendo identificadas 2 coortes retrospectivas (Tabela 7).

No estudo de desenvolvido por Sohn et al., OCT apresentou vantagens em relação ao ultrassom visto que detectou maior área total de prolapso tecidual comparado com IVUS (4,31 vs 0,76, $p < 0,001$) e apresentou maior taxa de detecção de prolapso tecidual (59,9 vs 5,8, $p < 0,001$). Em um estudo de coorte retrospectiva, Wang et al. definiram OCT

como padrão quando comparado à Angiografia (CA) e ao ultrassom (IVUS), relatando que CA apresentou especificidade de 50,9% para calcificação e sensibilidade de 95,1%, enquanto IVUS apresentou sensibilidade de 74,5%.

Tabela 7. Resumo dos resultados reportados para avaliação da placa de aterosclerose.

Estudo	Tipo de estudo	N participantes (N homens)	Conclusão
Sohn, 2015 ⁴³	Coorte retrospectiva	38 (26)	OCT detectou maior área de prolapso tecidual (4,31) comparado com IVUS (0,76) e maior taxa de detecção de prolapso tecidual (59,9 vs 5,8)
Wang, 2017 ⁴⁵	Coorte retrospectiva	440 (363)	Comparado com OCT, CA apresentou para calcificação especificidade de 50,9% e sensibilidade de 95,1%, e IVUS 100% especificidade e 74,5% sensibilidade.

OCT: Tomografia de Coerência Óptica; IVUS: Ultrassom Intravascular; CA: Angiografia Coronária.

Além disso, estudo de Kubo, 2011³⁸ com pacientes com angina estável utilizou OCT como padrão para a detecção de fibroateroma de capa fina, verificando que IVUS apresenta menor especificidade e sensibilidade para detecção desse tipo de lesão. Resultados semelhantes foram apresentados por Takahashi, 2013⁴⁰, em que além de fibroateromas de capa fina, IVUS demonstrou menor acurácia para detecção de placas lipídicas..

Para detecção de calcificação, OCT apresentou especificidade de 100%, assim como IVUS utilizando escala cinza e superior ao IVUS de histologia virtual⁴⁶.

Para a identificação de estenose coronariana, o OCT mostrou maior acurácia em relação ao IVUS, embora a diferença não tenha sido estatisticamente significativa. No entanto, quando é realizada análise de subgrupo apenas com vasos de pequeno calibre, observa-se que o OCT tem maior capacidade de detectar estenose coronariana ($p = 0,04$)³⁹. Para detecção de isquemia, embora o IVUS tenha apresentado maior sensibilidade, o OCT apresentou maior acurácia devido à alta diferença no valor de especificidade apresentado pelos testes⁴⁷.

Em estudos realizados ex vivo, o OCT e IVUS foram analisados utilizando análises histológicas como padrão ouro. No estudo de Kume (2006)³⁵, OCT apresentou maior sensibilidade para caracterizar placas lipídicas (85% vs 59%, $p = 0,03$). Resultados de Kawasaki, 2006³⁶ mostram que o OCT apresenta maiores valores de sensibilidade e

especificidade para todos os tipos de placas avaliadas (calcificação, fibrosas e lipídicas). Segundo Rieber, 2006³⁴, IVUS apresentou melhores valores de sensibilidade e especificidade apenas para detecção de placas de cálcio. OCT apresentou maior correlação com a histologia com relação à medida da área luminal, espessura intimal e espessura da íntima-média, em comparação ao IVUS³³. Para a detecção de ateromas em geral, bem como fibroateroma de capa fina, o OCT apresentou melhores dados de acurácia⁴¹.

QUESTÃO 2. Qual o impacto de OCT comparado com angiografia coronária ou IVUS para guiar ICP na incidência de MACE e recorrência de IAM?

Duas revisões avaliaram a incidência de MACE comparando a tecnologia utilizada para guiar a ICP (Tabela 8).

Buccheri et al., que incluiu 7 estudos de OCT, compreendendo 1623 paciente, encontrou uma redução significativa de MACE no grupo de OCT comparado com CA (OR = 0,69, ICr 0,49 – 0,98). Já na comparação de OCT com IVUS o resultado não mostrou diferença entre os grupos (OR = 0,87, ICr 0,61 – 1,3).

Kuku et al., uma revisão que incluiu 6 estudos e 1288 pacientes, não encontrou diferença na incidência de MACE entre os grupos que utilizaram CA, IVUS ou OCT.

Para recorrência de IAM, as mesmas revisões sistemáticas foram identificadas, sendo apontada ausência de diferença entre OCT e CA e OCT e IVUS (Tabela 8).

Tabela 8. Resumo dos resultados reportados para MACE e recorrência de IAM.

Estudo	Tipo de estudo	N estudos (N participantes)	OR (ICr ou IC 95%)
MACE			
<u>OCT vs CA</u>			
Buccheri, 2017	RS e RM	27 (16880)	0,69 (0,49 – 0,98)
Kuku, 2017	RS e MD	4 (1753)	0,70 (0,49 – 1,00)
<u>OCT vs IVUS</u>			
Buccheri, 2017	RS e RM	27 (16880)	0,87 (0,61 – 1,30)
Kuku, 2017	RS e MD	2 (1028)	0,89 (0,46 – 1,73)
Recorrência de IAM			
<u>OCT vs CA</u>			
Buccheri, 2017	RS e RM	28 (15925)	0,80 (0,45 – 1,40)

Kuku, 2017	RS e MD	4 (1753)	0,70 (0,42 – 1,16)
<u>OCT vs IVUS</u>			
Bucheri, 2017	RS e RM	28 (15925)	1,10 (0,61 – 2,10)
Kuku, 2017	RS e MD	2 (1028)	0,56 (0,12 – 2,70)

OCT: Tomografia de Coerência Óptica; IVUS: Ultrassom Intravascular; CA: Angiografia Coronária, RS: revisão sistemática, RM: rede de metanálise, MD: metanálise direta, MACE: eventos cardiovasculares maiores, IAM: infarto agudo do miocárdio, OR: odds ratio, ICr: intervalo de credibilidade, IC: intervalo de confiança.

Foi identificada publicação do Pan-London, estudo observacional publicado em julho de 2018, com elevado tamanho amostral ($n = 87.166$) que comparou OCT, IVUS e CA para os desfechos MACE e incidência de IAM não contemplado por nenhuma das duas metanálises anteriores. Dessa forma, conduzimos a atualização da metanálise em rede realizada por Bucheri et al. com o objetivo de identificar se há mudança das conclusões após adição de Jones et al.³². Na metanálise em rede conduzida pelos autores deste dossiê foram incluídos 32 estudos, sendo 15 observacionais e 17 randomizados, num total de 105.048 pacientes.

Para MACE, a atualização corroborou resultados de Bucheri et al., mostrando que OCT é superior a CA, porém similar a IVUS. Diferente, de Bucheri et al., realizamos análises separando por tempo de follow-up (todas as durações, 1 e 2 anos) e por tipo de estudos (randomizados e observacionais): as análises para subgrupos demonstram que ao passo que estudos observacionais preservam as conclusões, quando considerados apenas estudos randomizados, a superioridade de OCT sobre CA não é identificada, o que pode ser justificado pelo reduzido tamanho amostral destes estudos (Tabelas 9 a 11).

Tabela 9. Tabela de consistência para MACE em 1 ano (triângulo inferior) e MACE em 2 anos (triângulo superior) em metanálises em rede conduzida pelos autores deste dossiê.

CA	0.729 (0.602, 0.873)	0.653 (0.437, 0.972)
0.688 (0.563, 0.809)	IVUS	0.897 (0.585, 1.378)
0.683 (0.470, 0.977)	0.994 (0.688, 1.471)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para MACE em 1 ano (triângulo inferior), OCT apresenta OR de 0,994 em relação à IVUS, enquanto para MACE em 2 anos (triângulo superior) apresenta um OR de 0,897 em relação à IVUS.

Tabela 10. Tabela de consistência para MACE independente do tempo de follow-up em metanálise em rede conduzida por autores deste dossiê.

CA	0.702 (0.595, 0.802)	0.696 (0.526, 0.931)
	IVUS	0.993 (0.734, 1.367)
		OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para MACE independente do tempo de follow-up, OCT apresenta OR de 0,993 em relação à IVUS.

Tabela 11. Tabela de consistência para MACE independente do tempo de follow-up, considerando apenas estudos randomizados (triângulo superior) e apenas estudos observacionais (triângulo inferior), em metanálise em rede conduzida por autores deste dossiê.

CA	0.604 (0.394, 0.852)	0.967 (0.355, 2.806)
0.738 (0.622, 0.879)	IVUS	1.607 (0.624, 4.506)
0.659 (0.486, 0.901)	0.893 (0.635, 1.246)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para MACE independente do tempo de follow-up, OCT apresenta OR de 1,607 em relação à IVUS (estudos randomizados) e de 0,893 em relação à IVUS (estudos observacionais).

Para IAM, a atualização corroborou resultados de Bucchieri et al., mostrando que é similar à CA e IVUS. Diferente, de Bucchieri et al., realizamos análises separando por tempo de follow-up (todas as durações, 1 e 2 anos) e por tipo de estudos (randomizados e observacionais). No entanto, análises para subgrupos não modificaram conclusões iniciais (Tabelas 12 a 14).

Tabela 12. Tabela de consistência para IAM em 1 ano (triângulo inferior) e IAM em 2 anos (triângulo superior) em metanálises em rede conduzida pelos autores deste dossiê.

CA	0.693 (0.423, 1.117)	0.687 (0.238, 1.669)
0.714 (0.498, 0.958)	IVUS	0.987 (0.325, 2.628)
0.590 (0.302, 1.125)	0.830 (0.416, 1.650)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para IAM em 1 ano (triângulo inferior) OCT apresenta OR de 0,830 em relação à IVUS, enquanto para IAM em 2 anos (triângulo superior) OCT apresenta OR de 0,987 em relação à IVUS.

Tabela 13. Tabela de consistência para IAM independente do tempo de follow-up em metanálise em rede conduzida por autores deste dossiê.

CA	0.719 (0.541, 0.930)	0.736 (0.437, 1.245)
	IVUS	1.029 (0.594, 1.826)
		OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para IAM independente do tempo de follow-up, OCT apresenta OR de 1,029 em relação à IVUS.

Tabela 14. Tabela de consistência para IAM independente do tempo de follow-up, considerando apenas estudos randomizados (triângulo superior) e apenas estudos observacionais (triângulo inferior), em metanálise em rede conduzida por autores deste dossiê.

CA	0.826 (0.418, 1.265)	1.718 (0.361, 8.341)
0.676 (0.476, 0.999)	IVUS	2.155 (0.425, 11.055)
0.662 (0.345, 1.138)	0.980 (0.469, 1.804)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para IAM independente do tempo de follow-up, OCT apresenta OR de 2,155 em relação à IVUS (estudos randomizados) e de 0,980 em relação à IVUS (estudos observacionais).

Para o desfecho combinado morte cardiovascular e IAM, não foram identificadas metanálises publicadas. Assim, nas metanálises conduzidas pelos autores deste dossiê foi identificada superioridade de OCT com relação à angiografia apenas para o follow-up de 1 ano e para análise independente do tempo de follow-up e tipo de estudo. Não foi identificado estudo de OCT em dois anos que reportou os dois desfechos (morte cardiovascular e IAM), permitindo a combinação (Tabelas 15 a 17).

Tabela 15. Tabela de consistência para morte cardiovascular e IAM para follow-up de 1 mês (triângulo superior) e de 1 ano (triângulo inferior), independente do tipo de estudo, em metanálise em rede conduzida por autores deste dossiê.

CA	0.603 (0.476, 0.755)	0.603 (0.312, 1.171)
0.602 (0.422, 0.832)	IVUS	1.006 (0.493, 1.985)
0.504 (0.256, 0.960)	0.836 (0.415, 1.681)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para morte cardiovascular e IAM, OCT apresenta OR de 0,603 em relação à CA (1 mês de follow-up) e de 0,504 em relação à CA (1 ano de follow-up).

Tabela 16. Tabela de consistência para morte cardiovascular e IAM independente do follow-up para estudos observacionais (triângulo superior) e para estudos randomizados (triângulo inferior), em metanálise em rede conduzida por autores deste dossiê.

CA	0.563 (0.390, 0.836)	0.482 (0.217, 1.065)
0.532 (0.108, 1.278)	IVUS	0.854 (0.360, 1.985)
0.523 (0.017, 8.084)	1.004 (0.057, 17.160)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para morte cardiovascular e IAM, OCT apresenta OR de 0,482 em relação à CA (estudos observacionais) e de 0,523 em relação à CA (estudos randomizados).

Tabela 17. Tabela de consistência para morte cardiovascular e IAM independente do follow-up e tipo de estudo (triângulo superior), em metanálise em rede conduzida por autores deste dossiê.

CA	0.569 (0.417, 0.768)	0.489 (0.242, 0.976)
	IVUS	0.857 (0.411, 1.789)
		OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para morte cardiovascular e IAM, OCT apresenta OR de 0,489 em relação à CA.

QUESTÃO 3. Qual o impacto de OCT comparado com angiografia coronária ou IVUS para guiar ICP na mortalidade por todas as causas e mortalidade por causas cardiovasculares?

Apenas um trabalho encontrado reportou resultados de mortalidade por todas as causas comparando de OCT com CA ou IVUS. Em seu estudo, Buccheri et al. reportou não haver diferença na taxa de morte entre os pacientes que realizaram ICP guiada por OCT ou CA ou IVUS (Tabela 18).

As revisões incluídas no presente dossiê avaliaram as taxas de morte cardiovascular entre grupos de pacientes que foram submetidos a ICP guiada por OCT ou CA ou IVUS. Os autores Buccheri et al. e Kuku et al. encontraram uma redução do risco de morte cardiovascular quando compararam OCT com CA (OR = 0,31, ICr 0,13 – 0,67 e OR = 0,40, IC 0,18 – 0,90, respectivamente). Na comparação de OCT versus IVUS, não houve diferença significativa entre os resultados (Tabela 18).

Tabela 18. Resumo dos resultados reportados para mortalidade por todas as causas e causas CDV.

Estudo	Tipo de estudo	N estudos (N participantes)	OR (ICr ou IC 95%)
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Mortalidade por todas as causas

OCT vs CA			
Buccheri, 2017	RS e RM	23 (13656)	0,61 (0,31 – 1,20)

OCT vs IVUS			
Buccheri, 2017	RS e RM	23 (13656)	0,81 (0,41 – 1,60)

Mortalidade por causas CDV

OCT vs CA			
Buccheri, 2017	RS e RM	21 (13398)	0,31 (0,13 – 0,67)

Kuku, 2017	RS e MD	3 (1513)	0,40 (0,18 – 0,90)
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OCT vs IVUS			
Buccheri, 2017	RS e RM	21 (13398)	0,66 (0,28 – 1,50)

Kuku, 2017	RS e MD	2 (1028)	0,56 (0,12 – 2,70)
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OCT: Tomografia de Coerência Óptica; IVUS: Ultrassom Intravascular; CA: Angiografia Coronária, RS: revisão sistemática, RM: rede de metanálise, MD: metanálise direta, CDV: cardiovascular, OR: odds ratio, ICr: intervalo de credibilidade, IC: intervalo de confiança.

Foi identificada publicação do Pan-London, estudo observacional publicado em julho de 2018, com elevado tamanho amostral ($n = 87.166$) que comparou OCT, IVUS e CA para o desfecho mortalidade todas as causas. Dessa forma, conduzimos a atualização da metanálise em rede realizada por Buccheri et al. com o objetivo de identificar se há mudança das conclusões após adição de Jones et al.³².

A atualização corroborou resultados de Buccheri et al., mostrando que OCT é similar à CA e IVUS em relação à MACE. Diferente, de Buccheri et al., realizamos análises separando por tempo de follow-up (todos as durações, 1 e 2 anos) e por tipo de estudos (randomizados e observacionais): as análises para subgrupos demonstram que ao passo que o tempo de follow-up e estudos randomizados não modificam conclusões iniciais, quando considerados apenas estudos observacionais, é identificada superioridade de OCT em relação à CA, o que pode ser justificado pelo elevado tamanho amostral destes estudos (Tabelas 19 a 21).

Tabela 19. Tabela de consistência para mortalidade por todas as causas em 1 ano (triângulo inferior) e mortalidade por todas as causas em 2 anos (triângulo superior) em metanálises em rede conduzida pelos autores deste dossiê.

CA	0.596 (0.450, 0.819)	0.620 (0.281, 1.294)
0.754 (0.596, 1.052)	IVUS	1.035 (0.449, 2.247)
0.519 (0.260, 1.049)	0.686 (0.326, 1.374)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para mortalidade por todas as causas em 1 ano (triângulo inferior) OCT apresenta OR de 0,686 em relação à IVUS, enquanto para mortalidade por todas as causas em 2 anos (triângulo superior) OCT apresenta OR de 1,035 em relação à IVUS.

Tabela 20. Tabela de consistência para mortalidade por todas as causas independente do tempo de follow-up em metanálise em rede conduzida por autores deste dossiê.

CA	0.690 (0.565, 0.863)	0.575 (0.329, 1.030)
	IVUS	0.829 (0.453, 1.511)
		OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para mortalidade por todas as causas independente do tempo de follow-up, OCT apresenta OR de 0,829 em relação à IVUS.

Tabela 21. Tabela de consistência para mortalidade por todas as causas independente do tempo de follow-up, considerando apenas estudos randomizados (triângulo superior) e apenas estudos observacionais (triângulo inferior), em metanálise em rede conduzida por autores deste dossiê.

CA	0.953 (0.356, 1.986)	40,659.996 (0.324, 218,867,894,448,156,670,000.000)
0.647 (0.526, 0.803)	IVUS	43,958.443 (0.314, 167,916,750,879,313,260,000.000)
0.537 (0.308, 0.921)	0.831 (0.458, 1.429)	OCT

Cada célula representa o efeito em odds ratio e intervalo de credibilidade 95%. Leia-se a intervenção da direita comparada à intervenção da esquerda. Assim, para mortalidade por todas as causas independente do tempo de follow-up, OCT apresenta OR de 43.958.443 (elevada incerteza) em relação à IVUS (estudos randomizados) e de 0,831 em relação à IVUS (estudos observacionais).

QUESTÃO 4. Qual o impacto de OCT comparado com angiografia coronária ou IVUS para guiar ICP na revascularização da lesão alvo e trombose do *stent*?

A necessidade de uma reintervenção na mesma lesão, ou seja, no segmento intra *stent*, foi avaliada entre paciente que realizaram ICP guiada por OCT, CA ou IVUS. Os resultados reportados por Buccheri et al. e Kuku et al. mostram semelhança entre as taxas de revascularização da lesão alvo (Tabela 22).

As revisões discutidas no presente dossiê avaliaram também a incidência de trombose de *stent* após ICP guiada por OCT, CA ou IVUS. Não houve diferença estatisticamente significativa entre resultados encontrados para este desfecho (Tabela 22).

Tabela 22. Resumo dos resultados reportados para revascularização da lesão alvo e trombose de *stent*.

Estudo	Tipo de estudo	N estudos (N participantes)	OR (ICr ou IC 95%)
Revascularização da lesão-alvo			
<u>OCT vs CA</u>			
Buccheri, 2017	RS e RM	23 (14197)	0,66 (0,35 – 1,20)
Kuku, 2017	RS e MD	2 (871)	1,07 (0,48 – 2,38)
<u>OCT vs IVUS</u>			
Buccheri, 2017	RS e RM	23 (14197)	0,89 (0,47 – 1,70)
Kuku, 2017	RS e MD	2 (1028)	0,99 (0,45 – 2,18)
Trombose de <i>stent</i>			
<u>OCT vs CA</u>			
Buccheri, 2017	RS e RM	24 (15736)	0,39 (0,09 – 1,30)
Kuku, 2017	RS e MD	3 (1513)	1,17 (0,40 – 3,43)
<u>OCT vs IVUS</u>			
Buccheri, 2017	RS e RM	24 (15736)	0,93 (0,23 – 3,60)
Kuku, 2017	RS e MD	2 (1028)	0,43 (0,06 – 2,95)

OCT: Tomografia de Coerência Óptica; IVUS: Ultrassom Intravascular; CA: Angiografia Coronária, RS: revisão sistemática, RM: rede de metanálise, MD: metanálise direta, OR: odds ratio, ICr: intervalo de credibilidade, IC: intervalo de confiança.

5 DOMÍNIO OPERACIONAL

O OCT deve ser operado apenas por profissionais que receberam treinamento devendo ser transportado, armazenado e operado de acordo com especificações.

5.1 Fatores humanos e treinamento

Todos os operadores devem receber treinamento antes de sua utilização. Além do treinamento para operar o aparelho, o operador deve tomar algumas precauções para preservar sua segurança. Dentre esses cuidados, destaca-se a prevenção da síndrome do túnel do carpo (STC) e problemas musculoesqueléticos, com as seguintes medidas:

- Mantenha as articulações em posições ótimas com uma postura equilibrada, evitando:
 - Posturas estáticas.
 - A utilização de força durante movimentos repetitivos.
 - Flexão ou desvio do punho.
- Posicione o teclado e o monitor de modo a minimizar os esforços por tentativa de alcance e alongamento.
- Faça pausas frequentes para dar tempo aos tecidos de se recuperar de posições incômodas e movimentos repetitivos

Para evitar quaisquer perigos potenciais de emissão de luz para si ou para os pacientes, as informações fornecidas nas etiquetas de segurança localizadas no sistema devem ser seguidas. É necessário executar os procedimentos somente conforme especificado nas instruções de utilização do fabricante.

5.2 Armazenamento, manutenção e descarte

Armazene o cateter a temperatura ambiente, em local seco e protegido da luz solar. O cateter destina-se exclusivamente à utilização única, não devendo ser reutilizado, reesterilizado ou reprocessado. Após a utilização, o cateter pode constituir um risco biológico potencial, devendo ser manuseado e descartado em conformidade com as práticas médicas adequadas e as leis e os regulamentos aplicáveis.

A assistência técnica dos componentes do sistema do aparelho deve ser realizada apenas por um representante de assistência qualificado. O sistema deve ser limpo conforme a programação de limpeza padrão da instituição, ou pelo menos a cada 30 dias durante a utilização normal. A manutenção do sistema consiste das seguintes etapas:

- Limpeza da conexão óptica do DOC e do cateter de imagem Dragonfly™.
- Substituição do adaptador óptico do DOC.
- Limpeza ou substituição do filtro de ar.
- Inspeção das conexões dos cabos expostos.
- Transferência dos arquivos de registro.
- Identificação da versão do software instalado.

5.3 Fatores de risco que poderão estar relacionados ao uso do equipamento médico-assistencial

Riscos e complicações poderão ocorrer em função do uso de todo e qualquer equipamento médico-assistencial. As complicações a seguir podem ocorrer como consequência da geração de imagens intravasculares:

- Espasmo da artéria coronária
- Angina instável
- Reação alérgica ao meio de contraste
- Dissecção, lesão ou perfuração arterial
- Formação de trombo, fechamento abrupto ou oclusão total
- Arritmias cardíacas anormais
- Embolia
- Infarto agudo do miocárdio
- Morte

6 RECOMENDAÇÕES E LIMITAÇÕES DA ANÁLISE

Embora a angiografia seja o método mais utilizado para realização da intervenção coronariana percutânea, existem novas tecnologias que apresentam maior acurácia e que desencadeiam melhores resultados clínicos ao paciente, como é o caso do OCT. Revisões sistemáticas seguidas por metanálise mostram que o uso de OCT pode apresentar benefícios clínicos em relação à angiografia isolada, em desfechos como mortalidade e MACE, principalmente quando considerados estudos de vida real que, apesar das potenciais limitações metodológicas, apresentam elevado poder estatístico para capturar benefícios em eventos pouco frequentes em follow-ups curtos como morte.

Dessa forma, considerando-se os resultados dos estudos de evidência clínica, bem como, toda a fundamentação das análises de custos efetividade e impacto orçamentário apresentadas neste dossiê, recomenda-se pela alteração da Diretriz de Utilização (DUT) já existente no Rol, a fim de incluir a cobertura da utilização de OCT para doenças coronarianas no sistema suplementar de saúde, em especial, como guia de ICP para pacientes que apresentam lesões complexas.

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APÊNDICES

Apêndice I – Busca de recomendações de agências de ATS.

Tabela 23. Busca de recomendações por OCT.

Agência de ATS/País	Termos	Documentos encontrados	Documentos selecionados
NICE/ Inglaterra e País de Gales	<i>optical coherence tomography</i>	21	1
SMC/ Escócia	<i>optical coherence tomography</i>	0	0
PBAC/ Austrália	<i>optical coherence tomography</i>	64	0
CADTH/ Canadá	<i>optical coherence tomography</i>	24	0
SBU/ Suécia	<i>optical coherence tomography</i>	2	0
IQWiG	<i>optical coherence tomography</i>	43	0

NICE – The National Institute for Health and Care Excellence; **SMC** – Scottish Medicine Consortium; **CADTH** – Canadian Agency for Drugs and Technologies in Health; **PBAC** – Pharmaceutical Benefits Advisory Committee; **SBU** – Swedish Council on Health Technology Assessment; **IQWiG** – Institute for Quality and Efficiency in Health Care

Apêndice II – Estratégias de buscas.

PubMed

		<i>Registros</i>
#1	((Arteriosclerosis[MH] OR Arteriosclerosis[TIAB] OR Atherosclerosis[MH] OR atherosclerosis[TIAB] OR Plaque, Atherosclerotic[MH] OR Angioplasty[MH] OR angioplasty[TIAB] OR "percutaneous coronary intervention"[TIAB] OR "Percutaneous Coronary Intervention"[MH] OR PCI[TIAB] OR intracoronary[TIAB] OR coronary[TIAB]))	546549
#2	("Tomography, Optical Coherence"[MH] OR "optical coherence tomography"[TIAB] OR OCT[TIAB])	44257
#3	(systematic review[TI] OR systematic literature review[TI] OR pooling project[TW] OR (systematic review[TIAB] AND review[PT]) OR "rapid review" OR "consensus development conference" OR "practice guideline" OR "clinical guideline"[TW] OR systematic[TW] OR systematically[TW] OR study selection[TW] OR (predetermined[TW] OR inclusion[TW] AND criteri*[TW]) OR exclusion criteri*[TW] OR "main outcome measures"[TW] OR "pooled data"[TW])	542102
#4	(meta analysable[TIAB] OR meta analysas[TIAB] OR meta analyse[TIAB] OR meta analysed[TIAB] OR meta analysei[TIAB] OR meta analysen[TIAB] OR meta analyser[TIAB] OR meta analysers[TIAB] OR meta analyses[TIAB] OR meta analysescohort[TIAB] OR meta analysespublication[TIAB] OR meta analysestype[TIAB] OR meta analysi[TIAB] OR meta analysia[TIAB] OR meta analysic[TIAB] OR meta analysing[TIAB] OR meta analysis[TIAB] OR meta analysis's[TIAB] OR meta analysis,[TIAB] OR meta analysis2[TIAB] OR meta analysisbone[TIAB] OR meta analysisdagger[TIAB] OR meta analyses[TIAB] OR meta analysisevaluating[TIAB] OR meta analysisif[TIAB] OR meta analysisindicated[TIAB] OR meta analysisintroduction[TIAB] OR meta analysisjr[TIAB] OR meta analysismoderate[TIAB] OR meta analysisof[TIAB] OR meta analysistrade[TIAB] OR meta analysisv[TIAB] OR meta analysisxs[TIAB] OR meta analyzed[TIAB] OR meta analyst[TIAB] OR meta analysticians[TIAB] OR meta analysts[TIAB] OR meta analysys[TIAB]) OR (meta analyzable[TIAB] OR meta analyze[TIAB] OR meta analyzed[TIAB] OR meta analyzes[TIAB] OR meta analyzing[TIAB]) OR (meta analytic[TIAB] OR meta analytical[TIAB] OR meta analytically[TIAB] OR	151865

	meta analytics[TIAB]) OR (metaanalyse[TIAB] OR metaanalysen[TIAB] OR metaanalyses[TIAB] OR metaanalysis[TIAB] OR metaanalysis'[TIAB] OR metaanalysisdata[TIAB] OR metaanalyst[TIAB]) OR (metaanalyze[TIAB] OR metaanalyzed[TIAB] OR metaanalyzedall[TIAB] OR metaanalyzing[TIAB]) OR (metaanalytic[TIAB] OR metaanalytical[TIAB] OR metaanalytically[TIAB]) OR "meta-analysis as topic"[MeSH] OR Meta-Analysis[PT])	
#5	((clinical[TIAB] AND trial[TIAB]) OR clinical trials as topic[MH] OR clinical trial[PT] OR random*[TIAB] OR random allocation[MH] OR therapeutic use[MeSH Subheading])	4962008
#6	Observational Study[PT] OR cohort studies[MH] OR cohort[TIAB] OR case-control studies[MH] OR (case[TIAB] and control[TIAB])	2097698
#7	letter[PT] OR editorial[PT] OR historical article[PT]	1794591
#8	(animals[MH:noexp] NOT (animals[MH:noexp] AND humans[MH]))	4403449
Busca 1	#1 and #2 and (#3 or #4) not #7 not #8	87
Busca 2	#1 and #2 and (#5 or #6) not #7 not #8 and "2015"[Date – Publication]: "3000"[Date – Publication]	773

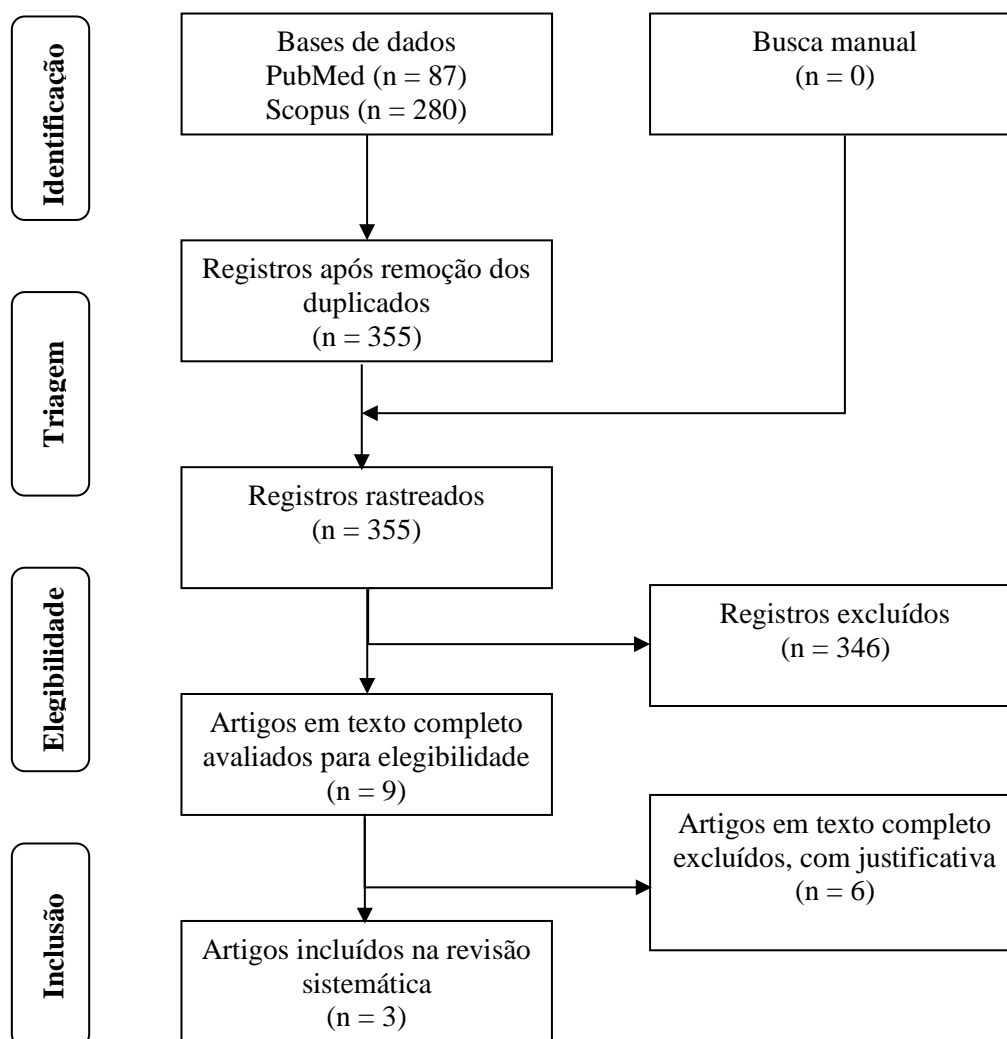
Scopus

		Registros
#1	TITLE-ABS-KEY(arteriosclerosis OR atherosclerosis OR angioplasty OR "percutaneous coronary intervention" OR PCI OR intracoronary OR coronary)	809,968
#2	TITLE-ABS-KEY("optical coherence tomography" OR OCT)	74,654
#3	TITLE-ABS-KEY("systematic review" OR "systematic literature review" OR "pooling project" OR "rapid review" OR "consensus development conference" OR "practice guideline" OR "clinical guideline" OR systematic OR systematically OR "study selection" OR (predetermined OR inclusion AND criteri*) OR "exclusion criteri*" OR "main outcome measures" OR "pooled data")	1,470,832
#4	TITLE-ABS-KEY("meta analyzable" OR "meta analysas" OR "meta analyse" OR "meta analysed" OR "meta analysei" OR "meta analysen" OR "meta analyser" OR "meta analysers" OR "meta analyses" OR "meta analysescohort" OR "meta analysespublication" OR "meta analysestype" OR "meta analysi" OR "meta analysia" OR "meta analysic" OR "meta	3,727,653

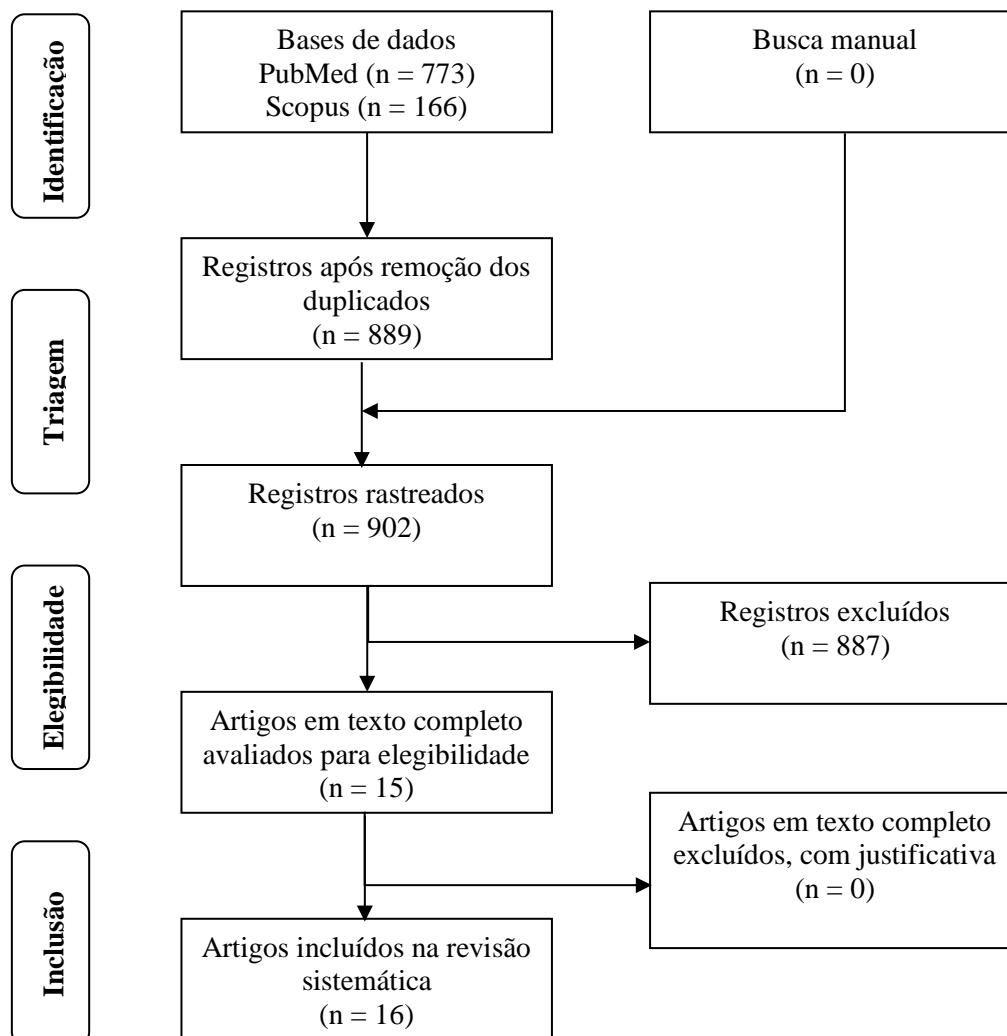
	analyzing" OR "meta analysis" OR "meta analysis's" OR "meta analysis" OR "meta analysis2" OR "meta analysisbone" OR "meta analysisdagger" OR "meta analyses" OR "meta analysisevaluating" OR "meta analysisif" OR "meta analysisindicated" OR "meta analysisintroduction" OR "meta analysisjr" OR "meta analysisimoderate" OR "meta analysisof" OR "meta analysistrade" OR "meta analysis" OR "meta analysisxs" OR "meta analyzed" OR "meta analyst" OR "meta analyticians" OR "meta analysts" OR "meta analysys") OR ("meta analyzable" OR "meta analyze" OR "meta analyzed" OR "meta analyzes" OR "meta analyzing") OR ("meta analytic" OR "meta analytical" OR "meta analytically" OR "meta analytics") OR (metaanalyse OR metaanalysen OR metaanalyses OR metaanalysis OR metaanalysis' OR metaanalysisdata OR metaanalyst) OR (metaanalyze OR metaanalyzed OR metaanalyzedall OR metaanalyzing) OR (metaanalytic OR metaanalytical OR metaanalytically) OR DOCTYPE(re)	
#5	TITLE-ABS-KEY (("clinical trials" OR "clinical trials as a topic" OR "randomized controlled trial" OR "Randomized Controlled Trials as Topic" OR "controlled clinical trial" OR "Controlled Clinical Trials as Topic" OR "random allocation" OR "randomly allocated" OR "allocated randomly" OR "Double-Blind Method" OR "Single-Blind Method" OR "Cross-Over Studies" OR "Placebos" OR "cross-over trial" OR "single blind" OR "double blind" OR "factorial design" OR "factorial trial")) OR (TITLE-ABS (clinical AND trial* OR trial* OR rct* OR random* OR blind*)) OR (INDEXTERMS ("clinical trials" OR "clinical trials as a topic" OR "randomized controlled trial" OR "Randomized Controlled Trials as Topic" OR "controlled clinical trial" OR "Controlled Clinical Trials" OR "random allocation" OR "Double- Blind Method" OR "Single-Blind Method" OR "Cross-Over Studies" OR "Placebos" OR "multicenter study" OR "double blind procedure" OR "single blind procedure" OR "crossover procedure" OR "clinical trial" OR "controlled study" OR "randomization" OR "placebo"))	6,675,704
#6	TITLE-ABS-KEY(posttest* OR "post test" OR "pre test" OR pretest* OR "quasi experiment*" OR quasiexperiment* OR timeseries OR "time series")	248,158
#7	TITLE-ABS-KEY("Observational Study" OR cohort OR (case and control))	1,623,096
#8	DOCTYPE(le OR ed)	3,156,684
#9	(TITLE-ABS-KEY(animals AND NOT (animals AND NOT humans)))	2,278,125
#10	INDEX(Medline)	23,563,473

Busca 1	#1 and #2 and (#3 or #4) and not #8 and not #9 and not #10	280
Busca 2	#1 and #2 and (#5 or #6) and not #8 and not #9 and not #10 and (PUBYEAR > 2014)	166

Apêndice III – Processo de seleção de revisões sistemáticas.



Apêndice IV - Processo de seleção de estudos primários.



Apêndice V – Registros excluídos na fase de elegibilidade.

Intervenção e/ou controle fora do escopo

Alsidawi S, Effat M, Rahman S, Abdallah M, Leesar M. The Role of Vascular Imaging in Guiding Routine Percutaneous Coronary Interventions: A Meta-Analysis of Bare Metal Stent and Drug-Eluting Stent Trials. *Cardiovasc Ther*. 2015;33(6):360–6.

Desfechos fora do escopo

Gutierrez-Chico JL, Serruys PW, Girasis C, Garg S, Onuma Y, Brugaletta S, et al. Quantitative multi-modality imaging analysis of a fully bioresorbable stent: a head-to-head comparison between QCA, IVUS and OCT. *Int J Cardiovasc Imaging*. 2012 Mar;28(3):467–78.

Tipo de estudo fora do escopo

Gerbaud E, Weisz G, Tanaka A, Kashiwagi M, Shimizu T, Wang L, et al. Multi-laboratory inter-institute reproducibility study of IVOCT and IVUS assessments using published consensus document definitions. *Eur Heart J Cardiovasc Imaging*. 2016 Jul;17(7):756–64.

Iannaccone M, D’Ascenzo F, Templin C, Omede P, Montefusco A, Guagliumi G, et al. Optical coherence tomography evaluation of intermediate-term healing of different stent types: systemic review and meta-analysis. *Eur Heart J Cardiovasc Imaging*. 2017 Feb;18(2):159–66.

Ma Y-F, Fam J-M, Zhang B-C. Critical analysis of the correlation between optical coherence tomography versus intravascular ultrasound and fractional flow reserve in the management of intermediate coronary artery lesion. *Int J Clin Exp Med* [Internet]. 2015;8(5):6658–67. Available from: <https://www.scopus.com/inward/record.uri?eid=2-s2.0-84937010481&partnerID=40&md5=13d47ed214b6350fa06a787828f2e733>

Voros S, Rinehart S, Qian Z, Joshi P, Vazquez G, Fischer C, et al. Coronary atherosclerosis imaging by coronary CT angiography: current status, correlation with intravascular interrogation and meta-analysis. *JACC Cardiovasc Imaging*. 2011 May;4(5):537–48.

TOMOGRAFIA DE COERÊNCIA OPTICA DE CORONARIAS

Parecer técnico

SUMÁRIO EXECUTIVO

Este parecer trata da avaliação das recomendações feitas por sociedades ou associações médicas nacionais e internacionais, bem como por agências governamentais e não governamentais de avaliação de tecnologias em saúde, sobre o uso da Tomografia de Coerência Óptica de coronárias para o diagnóstico de doença arterial coronariana obstrutiva. O foco desta avaliação é a indicação desta tecnologia para pacientes com doença arterial coronariana com objetivo de submissão do parecer técnico para a Agência Nacional de Saúde (ANS), com pedido de inclusão no Rol de procedimentos.

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SIGLAS

ACE	Agency for Care Effectiveness, Singapura
AETS	Agencia de Evaluación de Tecnologías Sanitarias, Espanha
AETSA	Agencia de Evaluación de Tecnologías Sanitarias da Andaluzia, Espanha
AGENAS	Agenzia Nazionale per I Servizi Sanitari Regionali, Itália
AHRQ	Agency for Healthcare Research and Quality, EUA
AHTA	Adelaide Health Technology Assessment, Austrália
AHTAPol	Agency for Health Technology Assessment in Poland, Polônia
AQuAS	Agencia de Qualitat i Avaluació Sanitaries de Catalunya, Espanha
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures - Surgical, Australia
ASSR	Agenzia Sanitaria e Sociale Regionale REGIONE EMILIA-ROMAGNA, Italia
ATS	Avaliação de Tecnologias em Saúde
AVALIA-T	Galician Agency for Health Technology Assessment, Espanha
BCBS	Blue Cross Blue Shield, EUA
CADTH	Canadian Agency for Drugs and Technologies in Health, Canadá
CCI	Cleveland Clinic Innovations, EUA
CDE	Center for Drug Evaluation, Taiwan
CEM	Inspection Générale de la sécurité sociale (IGSS), Cellule d'expertise medicale, Luxemburgo
CENETEC	Centro Nacional de Excelencia Tecnológica em Salud, México
CMeRC	Charlotte Maxeke Research Consortium, África do Sul
CONITEC	Comissão Nacional de Incorporação de Tecnologias no SUS, Brasil
CRD	Centre for Review and Dissemination
CVZ	College Voor Zorgverzekering, Holanda
DAC	Doença Arterial Coronariana
DACEHTA	Danish Centre for Health Technology Assessment, Dinamarca
DEFACTUM	Social & Health Services and Labour Market, Dinamarca
ECRI	Emergency Care Research Institute, EUA
FinCCHTA	Finnish Coordinating Center for Health Technology Assessment, Finlândia
FinOHTA	Finnish Office for Health Technology Assessment, Finlândia
G-BA	The Federal Joint Committee (Gemeinsamer Bundesausschuss), Alemanha
GOeG	Gesundheit Österreich GmbH, Áustria
HAD-Uruguay	Health Assessment Division, Ministry of Public Health, Uruguai
HAS	Haute Autorité de Santé (Lead Partner), França
HealthPACT	Health Policy Advisory Committee on Technology, Austrália
HIQA	Health Information and Quality Authority, Irlanda
HIS	Healthcare Improvement Scotland, Scotland
HQO	Evidence Development and Standards Branch, Canadá
IACS	Health Sciences Institute in Aragon, Espanha
IECS	Institute for Clinical Effectiveness and Health Policy, Argentina
IETS	Instituto de Evaluación Tecnológica em Salud, Colombia

IHE	Institute of Health Economics, Canadá
INEAS	National Authority for Assessment and Accreditation in Healthcare, Tunísia
INESSS	Institut national d'excellence en santé en services, Canadá
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Alemanha
IVUS	Intravascular Ultrasound
KCE	Belgian Health Care Knowledge Centre, Bélgica
LBI-HTA	Ludwig Boltzmann Institute for Health Technology Assessment, Áustria
MaHTAS	Health Technology Assessment Section, Ministry of Health Malaysia, Malásia
McGill-TAU	Technology Assessment Unit of the McGill University Health Centre, Canadá
NECA	National Evidence-based Healthcare Collaborating Agency, Korea
NICE	National Institute for Health and Care Excellence, Reino Unido
NIHR	National Institute for Health Research, Reino Unido
NIPH	Norwegian Institute of Public Health, Noruega
OCT	Optical Coherence Tomography
OSTEBA	Basque Office for Health Technology Assessment, Espanha
PBAC	Pharmaceutical Benefits Advisory Committee, Austrália
PTAC	Pharmacology and Therapeutics Advisory Committee, Nova Zelândia
RCHD	Republican Centre for health Development, Cazaquistão
SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services, Suécia
SCA	SCA: Síndrome Coronariana Aguda
SFOPH	Swiss Federal Office of Public Health, Suíça
SMC	Scottish Medicines Consortium, Escócia
TCE	TCE: Tronco de Coronária Esquerda
TLV	The Dental and Pharmaceutical Benefits Agency, Suécia
UVT HTA	Unit in A Gemelli Teaching Hospital, Itália
ZIN	Zorginstituut Nederland, Holanda
ZonMw	The Netherlands Organization for Health Research and Development, Holanda

1 PROBLEMA

1.1 Descrição das condições de saúde relacionadas à tecnologia

A doença arterial coronariana (DAC) continua sendo a principal causa de morte em todo o mundo. O risco de desenvolvimento de DAC ao longo da vida está ligado a etnia, idade, sexo, região geográfica, hábitos de vida e a presença de fatores de risco cardiovascular. Estima-se que ela surja em 38-51% dos homens e em 12 a 33% das mulheres ao longo da vida.¹ A suspeita ocorre quando há sintomas agudos (Síndrome coronariana aguda) ou crônicos (angina estável) da doença, geralmente manifestados através da presença de desconforto torácico.

Ocasionalmente é diagnosticada através de testes de screening rotineiros.¹

1.1.1 Angina estável

A angina estável é uma manifestação clínica importante da doença arterial coronariana. O diagnóstico frequentemente inclui testes funcionais ou anatômicos feitos antes da indicação de uma coronariografia invasiva, que é reservada para pacientes com moderada ou alta probabilidade de DAC. Apesar disso apenas cerca de 41% dos pacientes que são submetidos a coronariografia invasiva de fato são diagnosticados com DAC obstrutiva.¹

1.1.2 Síndrome coronariana aguda

A manifestação aguda da DAC é denominada de síndrome coronariana aguda (SCA) e refere-se ao infarto agudo do miocárdio (IAM) com ou sem supra desnivelamento do segmento ST (SST) e à angina instável. Braunwald definiu 5 causas principais de síndromes coronarianas agudas: obstrução mecânica, obstrução dinâmica, trombose, inflamação ou infecção e aumento da demanda ou diminuição da oferta de oxigênio. A causa mais frequente, entretanto, relaciona-se aos eventos trombóticos resultantes de uma ruptura ou de uma expansão súbita de uma placa de ateroma, não necessariamente obstrutiva, levando a uma obstrução parcial ou total do leito coronariano.^{2,3}

A OCT de coronárias tem um aspecto único que favorece sua utilização em pacientes com Síndrome Coronariana Aguda (SCA), pois diferentemente do USIV é capaz de detectar o local de ruptura de placa de ateroma e a presença de trombos, tendo papel importante quando a coronariografia é aparentemente normal em pacientes com manifestação clínica e laboratorial de SCA.⁴

1.2 Padrão ouro para o diagnóstico das condições de saúde relacionadas à tecnologia

A coronariografia invasiva tem sido o padrão ouro para a avaliação da gravidade da obstrução coronariana nos últimos 50 anos e é utilizada como base para recomendação de procedimentos de revascularização percutâneos ou cirúrgicos. Sua principal limitação repousa no fato de que sozinha a coronariografia não é capaz de oferecer informações funcionais ou qualitativas sobre as lesões coronarianas. Como consequência diversas lesões são tratadas desnecessariamente quando a indicação da revascularização não é guiada por métodos funcionais ou outros métodos de imagem.⁵

2 TECNOLOGIA

2.1 Descrição técnica detalhada da tecnologia

A OCT é um método de imagem intravascular que fornece imagens tomográficas de alta definição, através da emissão de um feixe de luz infravermelha com comprimento de onda de cerca de 1.300nm. Sua penetração nos tecidos é de 1 a 3 mm, comparado aos 4 a 8 mm alcançados pelo USIV. Sua resolução axial é 10 vezes maior (10 a 15 µm) que a obtida pelo USIV (100 a 150 µm), com menos artefatos na imagem. Sua resolução lateral é de 12 a 18 µm contra 150 a 200 µm do USIV. Estas propriedades conferem a OCT uma alta resolução, com capacidade de gerar imagens de alta qualidade com definição “próxima do nível histológico”.

De um modo geral ambas as modalidades de imagem servem aos mesmos propósitos, quer seja de avaliar com mais precisão o grau de estenose de uma lesão coronária moderada/ambígua, ou

ainda como instrumental adjunto, para guiar a realização de intervenções complexas, permitindo dimensionar de forma mais acurada o vaso a ser tratado e avaliar o resultado do procedimento, visando sempre obter o melhor grau de expansão e aposição possível, a fim de reduzir a incidência de novas intervenções na lesão-alvo.

Embora de um modo geral a OCT e o USIV compartilhem de indicações clínicas semelhantes, estes métodos, pela natureza distinta de suas imagens, também partilham diferenças e vantagens/desvantagens. Em linhas gerais, a utilização da luz infravermelha pela OCT favorece a obtenção de imagens com maior resolução superficial (ou axial) em relação ao USIV, com magnificação das imagens em até 10 vezes. Com isso, a interpretação das imagens bem como a realização de mensurações no lumen coronário se tornam mais fáceis e precisas. Também, devido a elevada velocidade de aquisição das imagens com a OCT (100 quadros coronários por segundo, versus 30 quadros por segundo com o USIC), pode-se realizar reconstruções tridimensionais da artéria coronária com grande precisão e qualidade, o que tem sido bastante explorado no campo das bifurcações coronárias e nas análises tardias de stents bioabsorvíveis.

A realização da OCT demanda injeção (“*flush*”) de solução de contraste iodado durante a aquisição das imagens, para remover o sangue do lumen vascular e diminuir os artefatos provocados pelo sangue diante da luz infravermelha. Portanto, a realização de OCT é limitada em pacientes com importante disfunção renal, em função da necessidade de maior volume de contraste; nos indivíduos com grave disfunção ventricular, devido à sobrecarga de volume; e na avaliação de lesões aorto-ostiais, uma vez que tecnicamente não se consegue bloquear adequadamente o fluxo sanguíneo neste cenário.

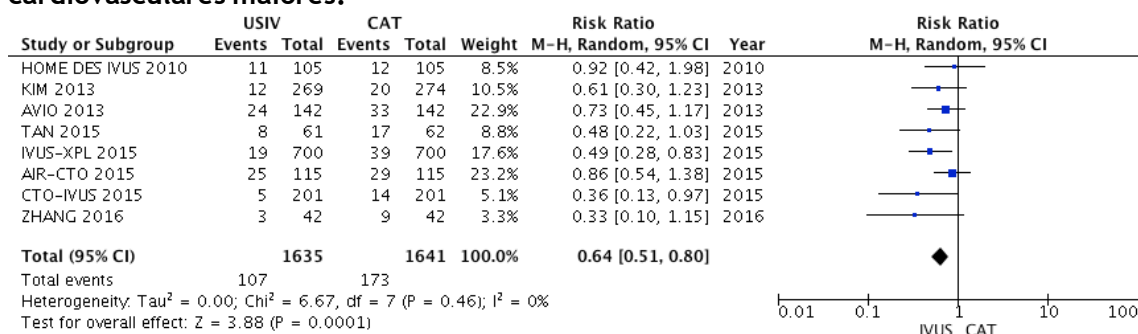
2.2 Tecnologia alternativa

O ultrassom intravascular (USIV) é a principal tecnologia alternativa à OCT. O USIV é uma modalidade de imagem ultrasonográfica invasiva que permite visualizar a estrutura da parede vascular, identificando acuradamente a presença da DAC nos seus diferentes estágios e as alterações dinâmicas do vaso coronário antes, durante e após a intervenção coronária percutânea. O cateter de ultrassom tem incorporado na sua extremidade um transdutor

miniaturizado, o qual possui um ou múltiplos cristais constituídos de cerâmica, que produzem cerca de 1.800 rotações por minuto, emitindo feixes sonoros contra a parede arterial, os quais são parcialmente refletidos de volta ao cateter, gerando a imagem monocromática.

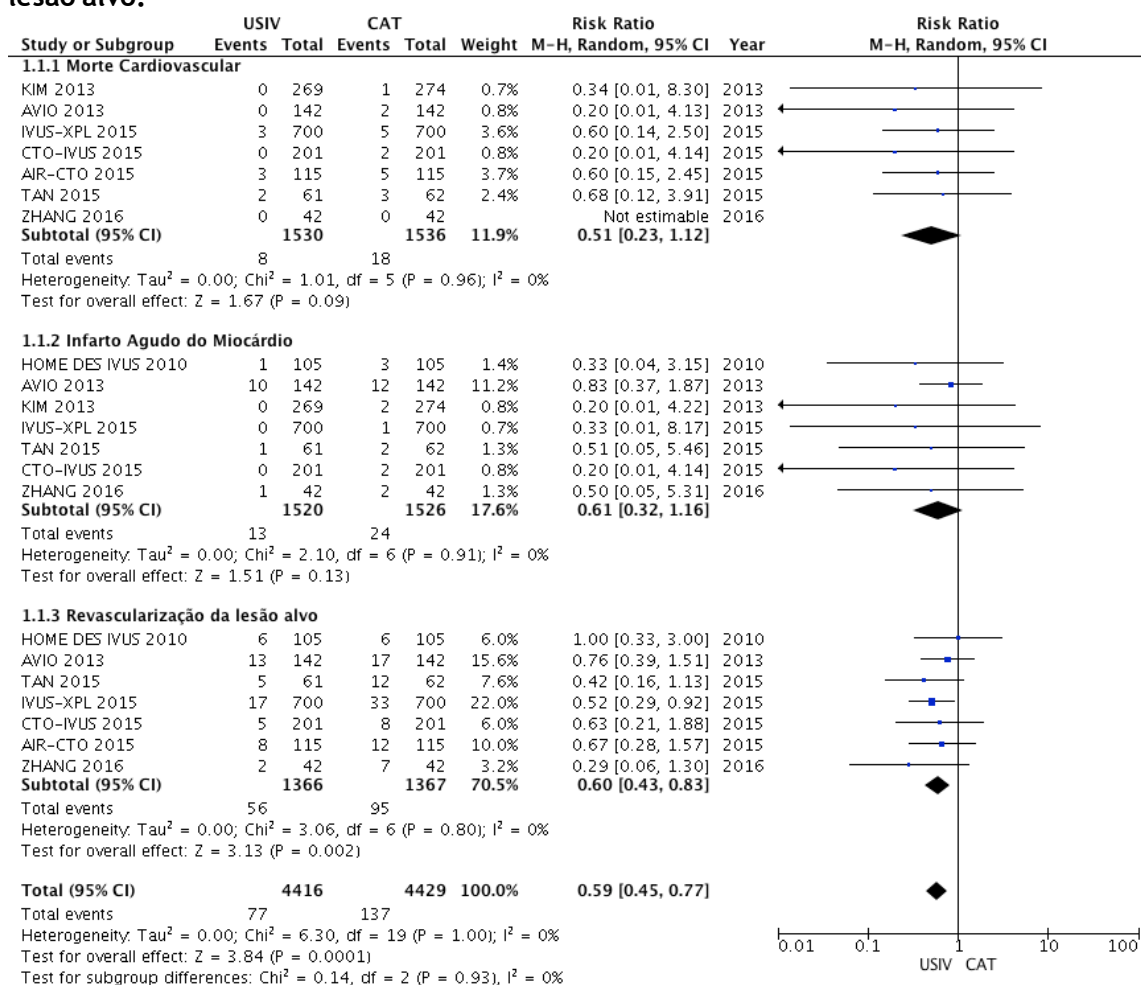
Está listado no Anexo I da RN nº 428, de 2017, e deve ser obrigatoriamente coberto por planos de segmentação hospitalar (com ou sem obstetrícia) e por planos-referência, conforme indicação do médico assistente. É amplamente utilizado para guiar a angioplastia e o implante de stent coronário na prática assistencial. A análise combinada dos dados de ensaios clínicos randomizados demonstram redução significativa de eventos cardíacos graves (Figura 1), principalmente em consequência da redução da incidência de revascularização da lesão alvo (Figura 2).

Figura 1: Comparação do efeito da coronariografia guiada ou não por USIV em desfechos cardiovasculares maiores.



Fonte: Raber 2018⁶

Figura 2: Comparação do efeito da coronariografia guiada ou não por USIV na incidência dos desfechos clínicos morte cardiovascular, infarto agudo do miocárdio e revascularização da lesão alvo.



Fonte: Raber 2018⁶

A incorporação da OCT na prática assistencial como alternativa ao USIV depende pelo menos da demonstração de sua não inferioridade ou equivalência ao USIV para guiar a conduta terapêutica na abordagem de pacientes com doença coronariana, ou de sua superioridade ao USIV na abordagem de lesões coronarianas onde o USIV tem papel limitado.

2.3 Tecnologias de apoio

A incorporação da OCT na prática assistencial deve considerar não somente a sua equivalência a tecnologias alternativas hoje listadas no rol de procedimentos da ANS, mas primariamente a sua

superioridade às tecnologias de apoio, quando utilizadas isoladamente. Neste contexto, a coronariografia é a principal tecnologia de apoio para realização da OCT.

3 OBJETIVOS

Avaliar as recomendações feitas por sociedades médicas nacionais e internacionais e pelas principais agências de avaliação de tecnologias do globo quanto a utilização da Tomografia de Coerência Óptica de coronárias em relação ao ultrassom intravascular na abordagem de pacientes com lesão coronariana aguda ou crônica.

4 MÉTODO

4.1 Objetos da avaliação

População: Angina estável ou síndrome coronariana aguda

Intervenção: Coronariografia guiada por tomografia de coerência óptica de coronárias (OCT)

Comparação 1: Coronariografia isolada

Comparação 2: Coronariografia guiada por ultrassom intravascular (USIV)

Desfechos clínicos: eventos cardíacos graves não fatais, infarto agudo do miocárdio, trombose de stent, óbito por qualquer causa, óbito por causa cardiovascular, revascularização da lesão alvo

Desfechos intermediários: área luminal mínima intra stent

4.2 Desenho

Revisão rápida de diretrizes, consensus, avaliações de tecnologias em saúde e revisões sistemáticas sobre o tema, para as condições especificadas.

4.3 Estratégia de busca

Termos utilizados na busca: (systematic review or guideline or consensus or HTA or Health Technology Assessment) AND (Optical Coherence Tomography or OCT) AND (Coronary* or Coronary Artery Disease or Coronary Plaque or Coronary Angiography)

Fontes utilizadas: Google, medline, CRD, sites das agências de avaliações de tecnologia na América do Norte, América Latina, Europa, Ásia, África e Oceania (Tabela 1).

Tabela 1. Agências de Avaliação de Tecnologias em Saúde pesquisadas

LOCALIDADE	SIGLAS	INSTITUIÇÕES PESQUISADAS NA AMÉRICA DO NORTE
Canadá	CADTH	Canadian Agency for Drugs and Technologies in Health
Canadá	INESSS	Institut national d'excellence en santé en services
Canadá	McGill-TAU	Technology Assessment Unit of the McGill University Health Centre
Canadá	HQO	Evidence Development and Standards Branch
Canadá	IHE	Institute of Health Economics
EUA	ECRI	Emergency Care Research Institute
EUA	CCI	CLEVELAND CLINIC INNOVATIONS
EUA	BCBS	BLUE CROSS BLUE SHIELD
EUA	AHRQ	Agency for Healthcare Research and Quality
LOCALIDADE	SIGLAS	INSTITUIÇÕES PESQUISADAS NA AMÉRICA LATINA
Argentina	IECS	Institute for Clinical Effectiveness and Health Policy
Brasil	CONITEC	Comissão Nacional de Incorporação de Tecnologias no SUS
Colômbia	IETS	Instituto de Evaluación Tecnológica em Salud
México	CENETEC	Centro Nacional de Excelencia Tecnológica em Salud
Uruguai	HAD-Uruguay	Health Assessment Division, Ministry of Public Health
LOCALIDADE	SIGLAS	INSTITUIÇÕES PESQUISADAS NA EUROPA
Alemanha	G-BA	The Federal Joint Committee (Gemeinsamer Bundesausschuss)
Alemanha	IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Áustria	GOeG	Gesundheit Österreich GmbH
Áustria	LBI-HTA	Ludwig Boltzmann Institute for Health Technology Assessment
Bélgica	KCE	Belgian Health Care Knowledge Centre
Dinamarca	DEFACTUM	Social & Health Services and Labour Market
Dinamarca	DACEHTA	Danish Centre for Health Technology Assessment
Escócia	SMC	Scottish Medicines Consortium
Espanha	AETS	Agencia de Evaluación de Tecnologías Sanitarias
Espanha	AETSA	Agencia de Evaluación de Tecnologías Sanitarias de Andalucía
Espanha	AQuAS	Agencia de Qualitat i Avaluació Sanitaries de Catalunya
Espanha	IACS	Health Sciences Institute in Aragon
Espanha	AVALIA-T	Galician Agency for Health Technology Assessment
Espanha	OSTEBA	Basque Office for Health Technology Assessment
Finlândia	FinCCHTA	Finnish Coordinating Center for Health Technology Assessment
Finlândia	FinOHTA	Finnish Office for Health Technology Assessment
França	HAS	Haute Autorité de Santé (Lead Partner)
Holanda	ZIN	Zorginstituut Nederland
Holanda	ZonMw	The Netherlands Organization for Health Research and Development
Holanda	CVZ	College Voor Zorgverzekering
Irlanda	HIQA	Health Information and Quality Authority

Itália	AGENAS	Agenzia Nazionale per I Servizi Sanitari Regionali
Italia	ASSR	Agenzia Sanitaria e Sociale Regionale REGIONE EMILIA-ROMAGNA
Itália	UVT HTA	Unit in A Gemelli Teaching Hospital
Luxemburgo	CEM	Inspection Générale de la sécurité sociale (IGSS), Cellule d'expertise medicale
Noruega	NIPH	Norwegian Institute fo Public Health
Polônia	AHTAPol	Agency for Health Technology Assessment in Poland
Reino Unido	NICE	National Institute for Health and Care Excellence
Reino Unido	NIHR	National Institute for Health Research
Scotland	HIS	Healthcare Improvement Scotland
Suécia	TLV	The Dental and Pharmaceutical Benefits Agency
Suécia	SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services
Suíça	SFOPH	Swiss Federal Office of Public Health
LOCALIDADE	SIGLAS	INSTITUIÇÕES PESQUISADAS NA ÁFRICA
África do Sul	CMeRC	Charlotte Maxeke Research Consortium
Tunísia	INEAS	National Authority for Assessment and Accreditation in Healthcare
LOCALIDADE	SIGLAS	INSTITUIÇÕES PESQUISADAS NA OCEANIA
Austrália	AHTA	Adelaide Health Technology Assessment
Australia	ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures - Surgical
Austrália	HealthPACT	Health Policy Advisory Committee on Technology
Austrália	PBAC	Pharmaceutical Benefits Advisory Committee
Nova Zelândia	PTAC	Pharmacology and Therapeutics Advisory Committee
LOCALIDADE	SIGLAS	INSTITUIÇÕES PESQUISADAS NA ASIA
Cazaquistão	RCHD	Republican Centre for health Development
Korea	NECA	National Evidence-based Healthcare Collaborating Agency
Malásia	MaHTAS	Health Technology Assessment Section, Ministry of Health Malaysia
Singapura	ACE	Agency for Care Effectiveness
Taiwan	CDE	Center for Drug Evaluation

4.4 Critérios de inclusão e exclusão de referências

Foram incluídos nesta análise apenas diretrizes, consensus, revisões sistemáticas e avaliações de tecnologias em saúde com recomendações ou resultados relacionadas a utilização de OCT em pacientes com doença arterial coronária aguda ou crônica.

4.5 Seleção de referências

As referências foram agrupadas através do gerenciador de referências Endnote 8.0 e as duplicadas foram automaticamente eliminadas. Um revisor fez a seleção de referências com base na leitura do título e do abstract do artigo em relação a pergunta da avaliação. As referências excluídas desta avaliação encontram-se disponíveis no anexo deste parecer.

4.6 Coleta de dados e análise das evidências

As recomendações foram extraídas por um revisor e registradas em tabelas do documento word.

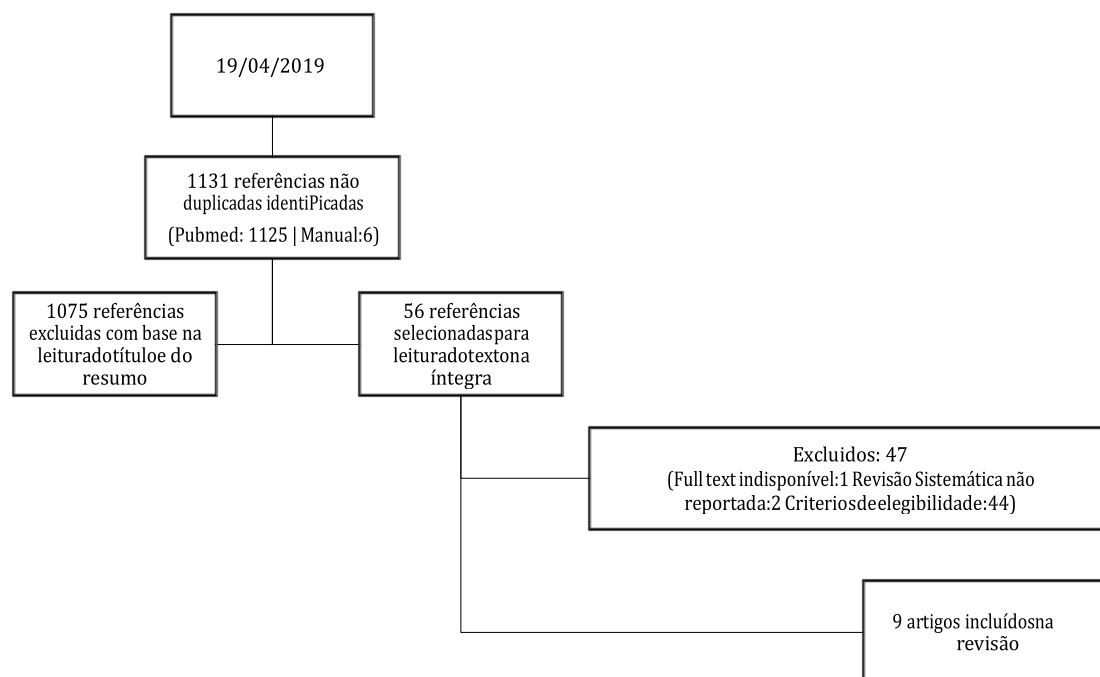
Foram aplicados os critérios do GRADE para análise do risco de vies dos estudos incluídos nas revisões sistemáticas e avaliações de tecnologia selecionadas, da consistência e da precisão dos resultados entre os estudos, do vies de publicação e do grau de aplicabilidade em relação a população alvo (“indirectness”).⁷

A qualidade das diretrizes foi avaliada apenas quanto ao rigor utilizado no seu desenvolvimento, já que é o domínio que tem demonstrado maior relação com variabilidade e influência nas recomendações.⁸ Para tanto foram aplicadas as seguintes perguntas:

1. As evidências foram localizadas e analisadas por meio de revisão sistemática?
2. Os critérios de seleção das evidências foram claramente descritos?
3. Os pontos fortes e os pontos fracos do corpo de evidências utilizado para sustentar as recomendações foram claramente descritos?
4. Os métodos utilizados para formulação das recomendações foram claramente descritos?
5. Os benefícios, efeitos colaterais e riscos potenciais foram considerados na formulação das recomendações?
6. Houve uma ligação explícita entre as recomendações e as evidências que as sustentam?
7. A diretriz foi revisada externamente por especialistas antes da publicação?
8. Um procedimento de atualização da diretriz foi fornecido?

5 RESULTADOS

5.1 Evidências selecionadas

Figura 3. Diagrama do fluxo de seleção e inclusão das evidências

Conforme apresentado na figura 3, acima, das 1131 referências identificadas (1125 no Pubmed e 6 por busca manual nos sites das agências de ATS), 1075 foram excluídas com base na leitura do título e do resumo do artigo. Das 56 referências restantes selecionadas para leitura do texto completo, apenas duas revisões sistemáticas,^{9,10} seis avaliações de tecnologias¹¹⁻¹⁶ e quatro consensos de especialidades médicas^{6,17-19} apresentavam informações relacionadas ao objeto desta revisão e foram incluídos nesta análise. Destas referências, uma avaliação de tecnologia do IECS foi excluída por falta de disponibilidade do texto na íntegra¹³, outra foi excluída por se tratar de uma avaliação de horizonte tecnológico, sem relato da revisão sistemática realizada (AGENAS)¹¹ e outra sem relato de evidências relacionadas a comparação da OCT com angiografia ou USIV.¹² A listagem das referências excluídas encontra-se em anexo a este parecer.

De todas as agências de avaliação de tecnologias pesquisadas a partir da busca manual nas páginas eletrônicas destes sites (Tabela 1), seis agências foram excluídas das estratégias de busca, duas por inacessibilidade a página web (CMeRC e INEAS) e quatro por restrição do idioma, disponível na língua local apenas (DEFACTUM, FinCCHTA, G-BA e MaHTAS).

5.2 Evidências incluídas

5.2.1 Qualidade das revisões sistemáticas e avaliações de tecnologias

Tabela 2. Critérios do GRADE para avaliação da qualidade dos estudos incluídos nas revisões sistemáticas para avaliação de eventos cardiovasculares graves

	Risco de viés nos resultados	Grau de imprecisão dos resultados	Grau de inconsistência dos resultados	Grau de aplicabilidade indireta	Risco de 19viés de publicação	Qualidade das evidências incluídas
Coronariografia guiada por OCT vs coronariografia isolada						
ATS Hayes 2016 ¹⁵	Baixo !	Moderado "	Baixo !	Baixo !	Baixo !	⊕⊕⊕⊖ moderada
ATS Maltoni 2016 ¹⁶	Baixo !	Moderado "	Baixo !	Baixo !	Baixo !	⊕⊕⊕⊖ moderada
RS Jiang 2019 ¹⁰	Moderado "	Moderado "	Baixo !	Baixo !	Baixo !	⊕⊕⊕⊖ moderada
Coronariografia guiada por OCT vs coronariografia guiada por USIV						
ATS NICE 2014 ¹⁴	Moderado "	Alto "	Baixo !	Baixo !	Baixo !	⊕⊕⊖⊖ baixa
RS Buccheri 2017 ⁹	Moderado "	Alto "	Baixo !	Baixo !	Baixo !	⊕⊕⊖⊖ baixa

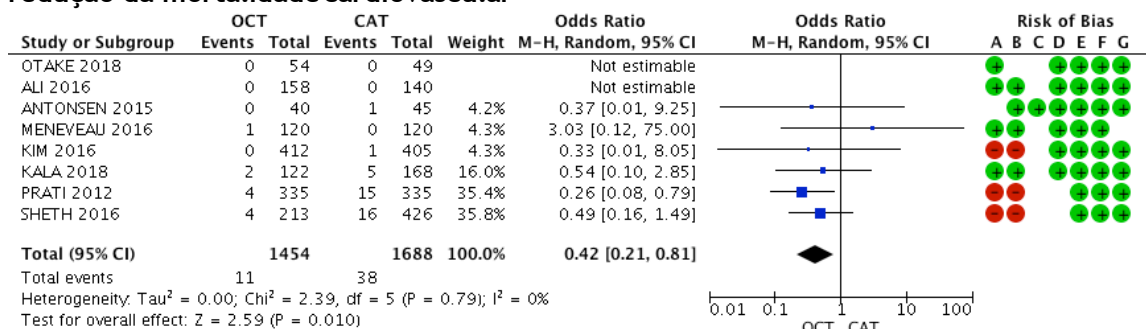
5.2.2 Qualidade das diretrizes e consensus

Tabela 3. Critérios do AGREE para avaliação do rigor metodológico das diretrizes selecionadas

Diretriz	1. Revisão sistemática?	2. Critérios de seleção descritos?	3. Pontos fortes e limitações	4. Método para recomendações	5. Riscos e benefícios considerados	6. Ligação entre recomendação e evidências	7. Revisão externa por especialistas	8. Procedimento de atualização
Levine 2013 ¹⁷	!	''	''	''	!	!	!	''
Raber 2018 ⁶	!	!	''	!	!	!	''	''
Ijsselmuiden 2018 ¹⁸	''	''	!	!	''	''	''	''
Onuma 2019 ¹⁹	''	''	''	''	!	!	''	''

5.3 Impactos da tecnologia em termos de benefícios clínicos para a morbimortalidade e para a qualidade de vida associada à condição de saúde em relação à tecnologia alternativa

Na revisão sistemática conduzida por Jiang e col.,¹⁰ a coronariografia guiada por OCT reduziu significativamente o número de óbitos por evento cardiovascular (OR 0,38 IC95% 0,19-0,74) em comparação com a coronariografia isolada.¹⁰ A figura 4 apresenta os resultados dos estudos considerados na revisão de Jiang e col, incluindo as informações do estudo de Meneveau 2016.²⁰

Figura 4. Eficácia da coronariografia guiada por OCT em relação a coronariografia isolada na redução da mortalidade cardiovascularRisk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Fonte: Jiang e col¹⁰

A revisão sistemática de Buccheri e col⁹ incluiu 17882 pacientes e fez comparações diretas e indiretas entre a coronariografia guiada por OCT, a coronariografia guiada por USIV e a coronariografia isolada. Esta revisão conclui que houve uma redução significativa na incidência de eventos cardíacos graves com a coronariografia guiada tanto por USIV quanto por OCT em relação a coronariografia isolada. Nenhuma diferença significativa foi observada, no entanto, entre as duas tecnologias para os desfechos clínicos óbito por causa cardiovascular, trombose de stent, revascularização da lesão alvo e infarto agudo do miocárdio.

O consenso europeu (Raber 2018) sobre o uso clínico de métodos de imagem intracoronária⁶ concluiu que a OCT e o USIV são tecnologias equivalentes e superiores a coronariografia isolada para guiar e otimizar procedimentos de angioplastia. Este consenso referenciou os ensaios clínicos randomizados de Kubo 2017²¹ e Ali 2016,²² que compararam diretamente os resultados da angioplastia guiada por USIV com os da angioplastia guiada por OCT com relação a desfechos clínicos e intermediários, respectivamente e na revisão sistemática de Buccheri e col.⁹ Este consenso conclui que ambas as modalidades podem identificar critérios de implante ótimo de stent tais como expansão, aposição e complicações, bem como mecanismos de falha de stent que não podem ser identificados pela coronariografia isoladamente. Entretanto as vantagens e desvantagens da OCT em relação ao USIV dependem da morfologia da lesão, de questões

técnicas relacionadas às tecnologias em si e das características clínicas dos pacientes, conforme detalhado na tabela abaixo.

Tabela 4. Vantagens e desvantagens da OCT em relação ao USIV

Vantagens da OCT	Desvantagens do USIV
Mais amigável com usuário em função da clareza das imagens e da facilidade de interpretação	Imagens de difícil interpretação
Análises acuradas e automatizadas das imagens prontamente disponíveis	Análise visual apenas
Resolução 10 x maior que USIV	Baixa resolução longitudinal
Melhor caracterização do tecido calcificado	Caracterização do tecido limitada
Mais adequado para detecção de trombos	Baixa capacidade de identificar trombos
Mais adequado para identificar a lesão culpada na suspeita de SCA uma vez que é capaz de detectar ruptura de placa, dissecções e trombos	Baixa capacidade de identificar a lesão culpada em pacientes com suspeita de SCA
Preditores de reestenose e trombose intra-stent bem estabelecidos	Baixa capacidade de identificar mal aposição do stent. Não detecta trombose intra-stent. Não avalia cobertura tecidual pela estrutura do stent.
Desvantagens da OCT	Vantagens do USIV
Uso adicional de contraste	Não há necessidade de uso adicional de contraste
Pré-dilatação e flush antes da aquisição da imagem podem ser necessários para limpar o lumen do vaso e permitir a visualização da parede	Possibilidade de aquisição de imagens pré-dilatação
Limitada para avaliar as bordas da placa de ateroma e o diâmetro do vaso delimitado pela membrana elástica externa, principalmente na presença de doença difusa	Pode guiar a escolha do tamanho do stent já que permite delimitar a extensão da placa de ateroma e o diâmetro do vaso, devido sua penetração tecidual
Limitada para avaliar lesões no óstio do TCE	Método de escolha na avaliação e tratamento de lesões no óstio do TCE
Dados limitados de literatura com relação ao impacto da angioplastia guiada por OCT em desfechos clínicos. As evidências dos efeitos benéficos da angioplastia guiada por OCT em desfechos clínicos são indiretas, obtidas a partir dos estudos de angioplastia guiada por USIV.	Larga experiência clínica, já que se encontra em uso por mais de 3 décadas. Dados vastos de literatura com relação ao impacto da angioplastia guiada por USIV em desfechos clínicos e em preditores de reestenose.

Fonte: Raber 2018.⁶

OCT: Optical Coherence Tomography; SCA: Síndrome Coronariana Aguda; TCE: Tronco de Coronária Esquerda; USIV: Ultrassom intravascular

Das Agências de avaliação de tecnologias pesquisadas, seis realizaram pareceres técnicos referentes a eficácia da coronariografia guiada por OCT para redução de desfechos clínicos ou intermediários. A maior parte destes pareceres não incluíram os principais ensaios clínicos de OCT que foram publicados apenas após 2015. Suas recomendações estão apresentadas na Tabela 5.

Tabela 5. Recomendações das agências de avaliação de tecnologias pesquisadas neste parecer e que reportaram pareceres técnicos relacionados à eficácia da OCT

AUTOR ANO	INSTITUIÇÃO	RECOMENDAÇÃO A RESPEITO DA CORONARIOGRAFIA GUIADA POR OCT EM RELAÇÃO A CORONARIOGRAFIA ISOLADA E A CORONARIOGRAFIA GUIADA POR IVUS
Raman 2013 ¹²	AHRQ	Nenhuma recomendação foi feita por falta de evidência disponível
2014 ¹⁴	NICE	OCT é uma tecnologia segura, mas com dados limitados de eficácia em relação a coronariografia isolada ou coronariografia guiada por outros métodos. Recomendação para utilização de forma restrita, em ambiente de pesquisa
Maltoni 2016 ¹⁶	ASSR	OCT é uma tecnologia segura, mas com eficácia em relação a coronariografia isolada ou coronariografia guiada por outros métodos ainda não comprovada.
Pareceres técnicos incompletos ou indisponíveis		
Paone 2010 ¹¹	AGENAS	Realizado apenas uma avaliação de horizonte tecnológico para OCT de coronárias para avaliação da microestrutura da placa de aterosclerótica vulnerável
Hayes 2016 ¹⁵	HAYES	Nenhuma recomendação reportada
Klappenbach 2017 ¹³	IECS	Parecer técnico indisponível

AGENAS: Agenzia Nazionale per I Servizi Sanitari Regionali, Itália; AHRQ: Agency for Healthcare Research and Quality, EUA; ASSR: Agenzia Sanitaria e Sociale Regionale REGIONE EMILIA-ROMAGNA, Itália; IECS: Institute for Clinical Effectiveness and Health Policy, Argentina; NICE: National Institute for Health and Care Excellence, Reino Unido; OCT: Optical Coherence Tomography.

Tabela 6. Recomendações das sociedades médicas de cardiologia intervencionista para uso da coronariografia guiada por OCT

INDICAÇÕES	SOCIEDADE MÉDICA
Avaliação da lesão culpada em pacientes com SCA	
Quando houver anormalidades no ECG, mas nenhuma evidência de trombo ou oclusão na coronariografia	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Identificação de erosão de placa ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Pós parada cardiorrespiratória com suspeita angiográfica de trombo recanalizado ⁶	European Association of Percutaneous Cardiovascular Interventions; Chinese Society of Cardiology
Avaliação de trombose de stent	
Quando houver recorrência de infarto em DA proximal para identificação da causa ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Identificação do mecanismo de trombose de stent em pacientes que evoluíram com IAM com SST. ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Identificação do mecanismo de trombose após trombosucção resultando em coronariografia normal em paciente com válvula mecânica ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology ⁶
Para guiar a angioplastia	
Angioplastia complicada com posição ou aposição do stent desconhecida no TCE ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Pós angioplastia na suspeita de fratura do stent por super expansão ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology ⁶
Angioplastia da porção distal do TCE ⁶	European Association of Percutaneous Cardiovascular

	Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Avaliação da aposição do stent após tratamento com rotablator em lesões complexas ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Avaliação da aposição do stent após extensiva dilatação de stent subdimensionado ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸
Identificação de anormalidades angiográficas inexplicadas	
Diferenciação de tromboembolismo de lesão local ⁶	European Association of Percutaneous Cardiovascular Interventions; ⁶ Chinese Society of Cardiology; ⁶ Netherlands Society of Cardiology ¹⁸

5.4 Eventos adversos relacionados a tecnologia em comparação à tecnologia alternativa

Os riscos envolvidos na obtenção de imagem vascular incluem os associados a todos os procedimentos de cateterismo. Embora estes eventos sejam raros eles podem ocorrer como consequência do posicionamento do cateter no lumen intravascular ou da injeção de contraste, seja pelo procedimento de coronariografia seja pelo procedimento de aquisição de imagens por outros métodos e podem necessitar de tratamento médico adicional, incluindo intervenção cirúrgica.

- Arritmias cardíacas;
- Dissecção, lesão ou perfuração arterial;
- Embolia;
- Enfarte agudo do miocárdio ou angina instável;
- Espasmo da artéria coronária;
- Formação de trombos;
- Morte;
- Reação alérgica ao meio de contraste.

Pacientes com alto risco para desenvolvimento de lesão renal podem se beneficiar mais do uso do ultrassom intravascular do que da OCT em função da necessidade de menor volume de contraste com o ultrassom.⁶

6 DISCUSSÃO

Os resultados dos estudos disponíveis devem ser interpretados no contexto das melhores práticas assistenciais. É importante considerar que stents de nova geração e refinamentos técnicos nos procedimentos de angioplastia tem permitido melhores resultados com as intervenções coronarianas percutâneas. Pacientes incluídos no estudo SYNTAX II, por exemplo, que utilizou stents com estruturas mais finas e angioplastia guiada por ultrassom intracoronário e por FFR (Fractional Flow Reserve), tiveram menor incidência de desfechos cardiovasculares quando comparados aos controles históricos.²³ Embora o papel do USIV neste estudo não possa ser estabelecido com clareza, ele pode ter contribuído para a baixa incidência de eventos cardíacos em uma população de pacientes com relativamente alto risco. Além disso, a análise combinada de diferentes ensaios clínicos randomizados tem demonstrado o impacto do USIV em desfechos clínicos.²⁴ Embora informações sobre o impacto da OCT em desfechos clínicos de médio e longo prazo ainda não estejam disponíveis, evidências indiretas dos estudos de ultrassom intracoronário sugerem que esta tecnologia tem eficácia semelhante ao USIV e pode ter um importante papel complementar importante na coronariografia na abordagem de pacientes com doença coronariana complexa e de difícil interpretação pelo ultrassom intracoronário, o que pode ser determinante na escolha da melhor conduta terapêutica para estes pacientes.⁹

A alta sensibilidade da OCT intravascular (100% vs. 33% do IVUS) na detecção de trombo intraluminal quando comparada à coronariografia,²⁵ traz informações adicionais na diferenciação de obstruções ocasionadas por placas calcificadas daquelas causadas por outras etiologias, com implicações na conduta a ser adotada. Sua capacidade de discriminar o mecanismo subjacente da SCA,^{25,26} impacta diretamente a estratégia de tratamento.^{27,28} A detecção, por exemplo, de causas de SCA não relacionadas à DAC, como artéria coronária espontânea e dissecação, pode evitar implantes desnecessários de stents. Da mesma forma a visualização de trombos em vasos calcificados confirma o diagnóstico da SCA e determina o tratamento percutâneo. Esta distinção não é possível pela coronariografia isoladamente ou em combinação com USIV devido a ambiguidade de suas imagens pela radiolucência. A OCT intravascular é considerada o método padrão-ouro para a detecção da ruptura da capa fibrosa,²⁵ com o dobro da sensibilidade apresentada pelo USIV. Nesse cenário clínico particular a

informação intravascular derivada da OCT a tornam o método ideal para definir a etiologia e a localização anatômica do vaso, o segmento culpado e confirmar ou excluir a presença de SCA.

É importante considerar que a realização de estudos randomizados para avaliação da superioridade da OCT em relação ao USIV na redução de desfechos clínicos em angioplastias guiadas por método de imagem não é de fácil execução, principalmente porque as vantagens da OCT em relação ao USIV estão relacionadas a lesões onde sabidamente o USIV não tem aplicabilidade. Onde o USIV é aplicável os resultados dos estudos randomizados são equivalentes para as duas tecnologias.

7 CONCLUSÃO

A OCT é um procedimento seguro conforme relatado por diferentes agências de avaliações de tecnologias e por sociedades médicas da especialidade, e que pode trazer benefício adicional a coronariografia para guiar a conduta terapêutica em pacientes com lesões complexas, principalmente quando há suspeita de um evento coronariano agudo em pacientes com coronariografia inconclusiva, onde o ultrassom vascular tem aplicabilidade bastante limitada. Revisões de literatura sugerem que há benefício clínico desta tecnologia em relação a coronariografia isolada na redução de óbitos por causa cardiovascular.

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