DCB and DES
Application in Dialysis Access

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DCB and DES

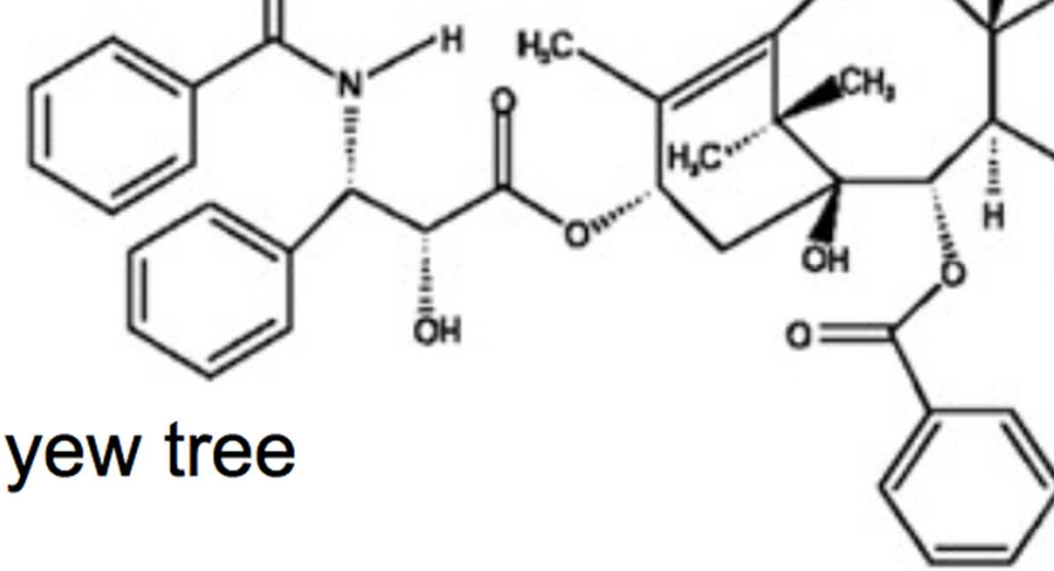
First experiences in Coronary beds

Approved devices for PAD

Most published experience in Access is DCB with Paclitaxel

Taxanes

a. Paclitaxel (taxol)



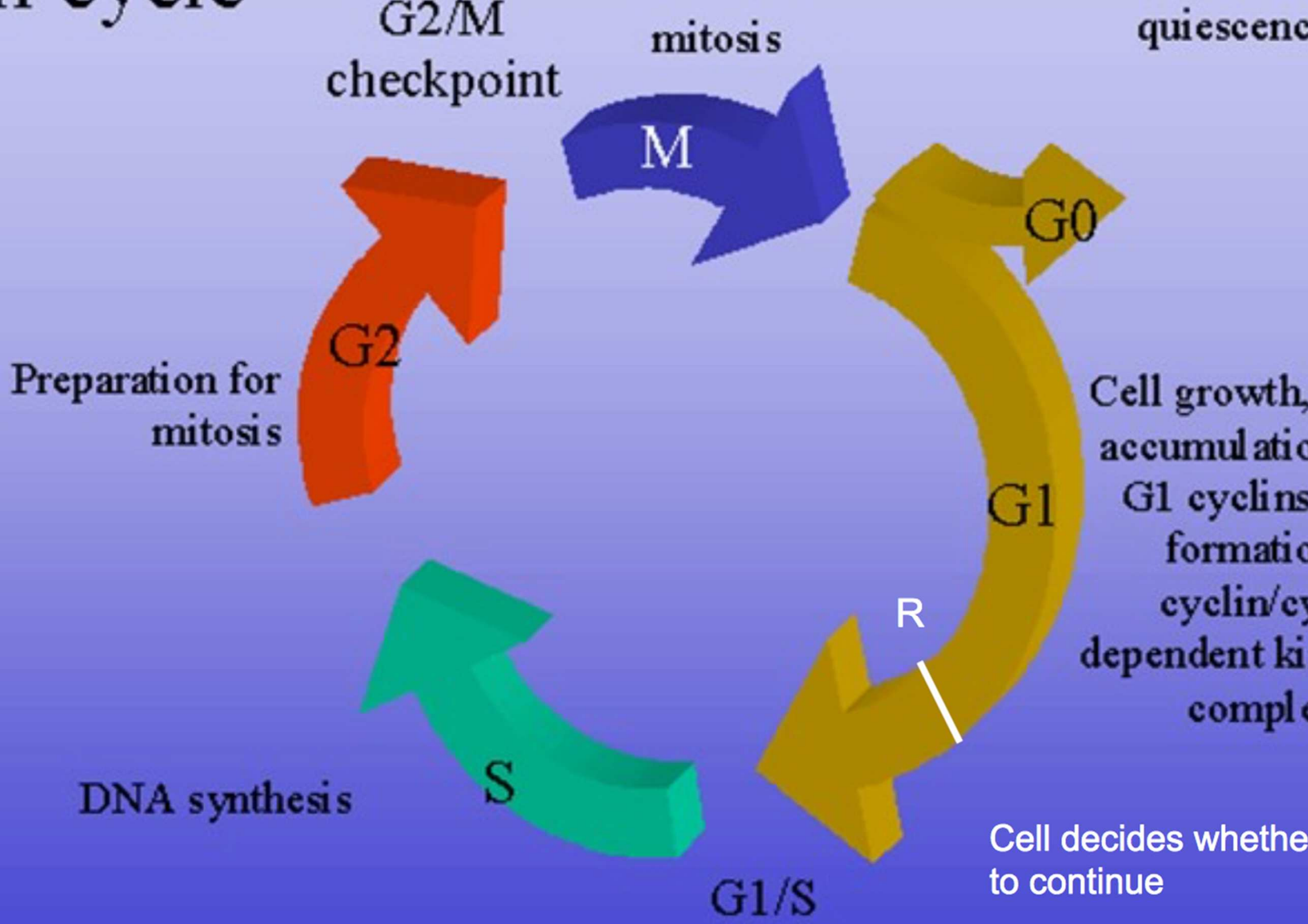
olated from the bark of the western yew tree

xanes

- binds to β-tubulin subunit *inside the* microtubules at distinct site from vinca alkaloids
- Promotes microtubule polymerization and inhibit depolymerization
- Irreversibly stabilizes cells in Mitosis leading to apoptosis.

clitaxel

- Interferes with normal microtubule growth by hyperstabilizing microtubule function--overly stable microtubules are dyfunctional
- Binds to β tubulin and promotes polymerization and stabilization of the


G2/M
checkpoint
mitosis
M
G0
G2
Preparation for
mitosis
Cell growth,
accumulatio
G1 cyclins
formatio
cyclin/cy
dependent ki
compl
G1
R
S
DNA synthesis
G1/S
Cell decides whethe
to continue

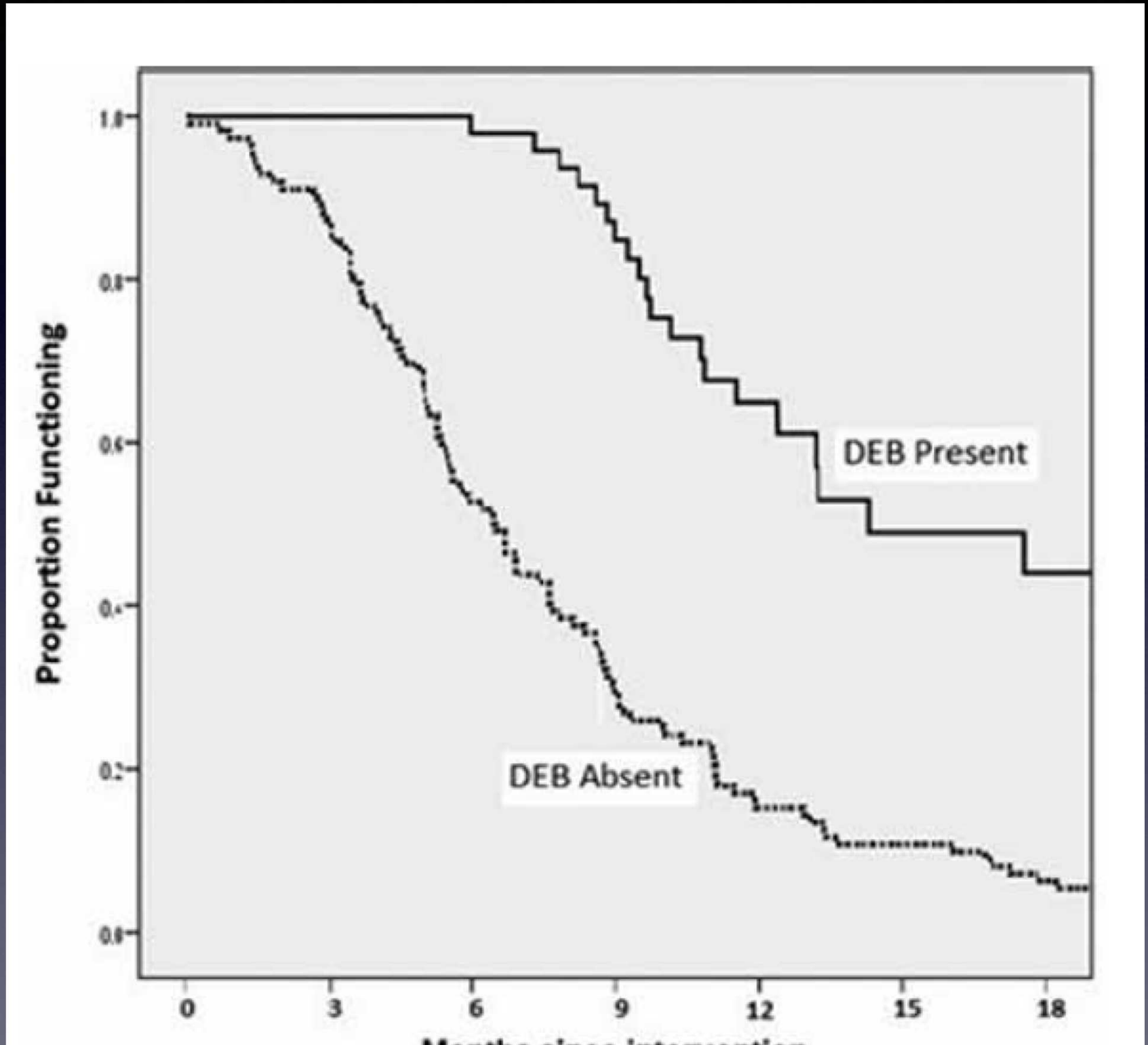
el drug-eluting balloons to recurrent in-stent stenoses in autogenous dialysis fis
ctive study.

, Zahid A, Burgess DC.

Retrospective review

37 AVF in stent restenotic lesions compared to previous experience

“Reintervention free” at 1 year 69% vs 19%

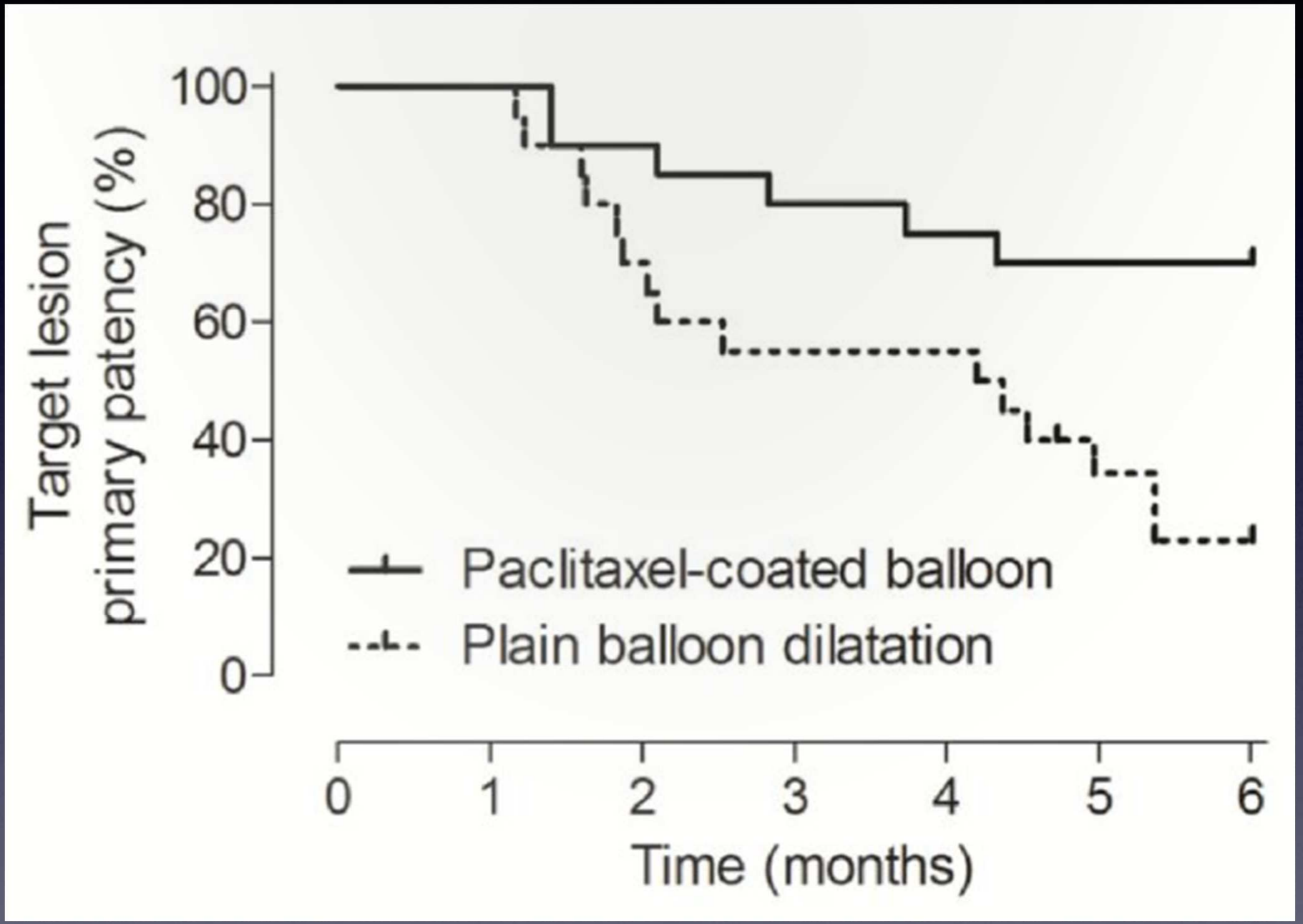

Proportion Functioning
1.0
0.8
0.6
0.4
0.2
0.0
DEB Present
DEB Absent
0
3
6
9
12
15
18

el-coated balloon angioplasty vs. plain balloon dilation for the treatment of failing
6-month interim results from a prospective randomized controlled trial.

, Karnabatidis D, Kitrou P, Spiliopoulos S, Christeas N, Siablis D.

Prospective randomized trial of DCB with PTX vs POBA

TLPP at 6 months 70% vs 25%


Target lesion primary patency (%)
100
80
60
40
20
0
Paclitaxel-coated balloon
Plain balloon dilatation
0
1
2
3
4
5
6
Time (months)

f a prospective randomized controlled trial.

Spiliopoulos S[2], Katsanos K[3], Papachristou E[4], Siablis D[1], Karnabatidis D[1].

015 Mar;84(3):418-23. doi: 10.1016/j.ejrad.2014.11.037. Epub 2014 Dec 15.

ting versus plain balloon angioplasty for the treatment of failing dialysis access: final
-effectiveness analysis from a prospective randomized controlled trial (NCT01174472)

Katsanos K[2], Spiliopoulos S[3], Karnabatidis D[3], Siablis D[3].

Prospective randomized trial on 40 patients

High pressure Balloons vs PTX

TLPP at 1 year 35% vs 5%

TLR free 308 days vs 161 days

Retrospective Analysis.

Spiliopoulos S[2], Papadimatos P[2], Christeas N[2], Petsas T[2], Katsanos K[2], Karnabatidis D[2].

Retrospective review of 39 patients, single arm

PTX

TLPP at 6 months 72%

eous angioplasty using a paclitaxel-coated balloon improves target lesion restenosis o
f autogenous radiocephalic fistulas: a pilot study.

g HC[2], Tseng CJ[3], Liu CP[4], Mar GY[5].

Prospective study of 20 lesions in 10 patients

PTX vs POBA

TLR free survival 251 days vs 103 days

TLPP at 6 months 705 vs. 0

TLPP at 1 year 20% vs 0

c Access. 2016 Mar-Apr;17(2):103-10. doi: 10.5301/jva.5000508. Epub 2016 Feb 5.

tematic review of drug eluting balloon angioplasty for arteriovenous haemodialysis access stenosis.

aja AZ[1], Cassidy DB[2], Al Shakarchi J[1], McGrogan DG[1], Inston NG[1], Jones RG[3].

uthor information

tract

KGROUND: Native or prosthetic arteriovenous (AV) fistulas are preferred for permanent haemodialysis (HD) access. These are ked with circuit steno-occlusive disease leading to dysfunction or even failure. Late failure rates have been reported as high as 50%. dard angioplasty balloons are an established percutaneous intervention for HD access stenosis. Reported restenosis rates remain and practice guidelines recommend a wide 6-month primary patency (PP) of at least 50% for any intervention. Neointimal rplasia is one of the main causes for access circuit stenosis. Drug eluting balloon (DeB) angioplasty has been proposed as an native intervention to reduce restenosis by local drug delivery and possible inhibition of this process.

POSE: To systematically assess the reported efficacy and safety of DeB angioplasty in percutaneous management of prosthetic and ogous HD access stenosis.

HODS: Protocol for the review was developed following the PRISMA-P 2015 statement. An electronic database (Medline, EMBASE, cal Trials.gov and Cochrane CENTRAL) search was conducted to identify articles reporting on the use of DeB intervention in HD AV ss. Backward and forward citation search as well as grey literature search was performed. The MOOSE statement and PRISMA statement were followed for the reporting of results. Data from the included studies comparing DeBs with non-DeBs were pooled g a random effects meta-analysis model and reported separately on randomised and non-randomised studies.

ULTS: Six studies reported on 254 interventions in 162 participants (mean 27 ± 10 SD). The pooled mean and median duration of w-up was 12 and 13 months (range 6-24 months). These comprised two randomised control trials (RCTs) and four cohort studies. cipant's mean age was 64 ± 5 years and 61% were male. Target lesions (TLs) ranged from under 2 mm to 5.9 mm and 51 were rted as de novo stenosis. Device failure described as wasting of the DeB was reported in two studies (55% and 92.8%). At 6 months P was reported between 70% to 97% for DeBs in the RCTs and cohort studies, and 0% to 26% for non-DeBs. TLs treated with s were associated with a higher primary patency at 6 months as compared to non-DeB balloons (RCTs: odds ratio [OR] 0.25, 95% 08 to 0.77 and I2 = 19%, cohort studies: OR 0.10, 95% CI 0.03 to 0.31 and an I2 = 20%). No procedure-related major or minor blications were reported.

CLUSIONS: Current literature reports DeBs as being safe and may convey some benefit in terms of improved rate of restenosis n used to treat AV access disease. However, this body of evidence is small and clinically heterogeneous. A large multicentre RCT help to clarify the role of DeBs in the percutaneous treatment of AV HD access stenosis.

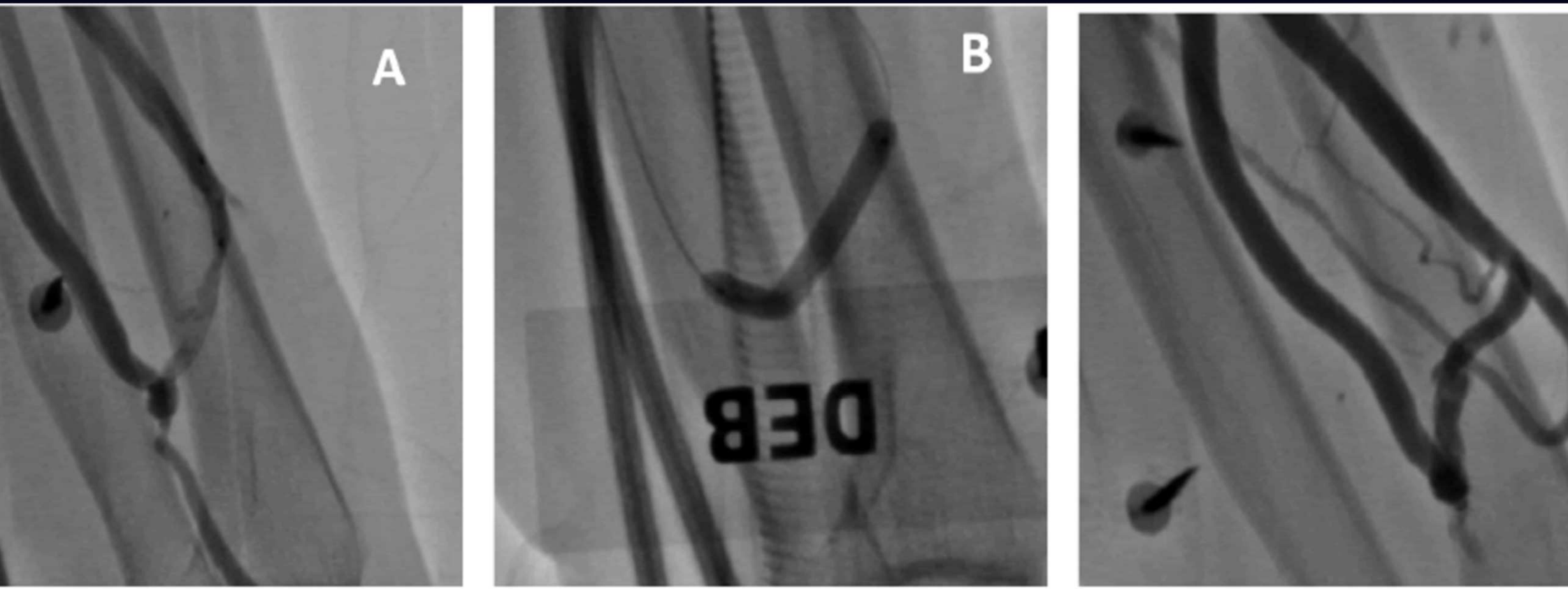
. 2014 Sep-Oct;15(5):338-43. doi: 10.5301/jva.5000211. Epub 2014 Feb 10.

ting balloon for the treatment of failing hemodialytic radiocephalic arteriovenous fistu
ce in the treatment of juxta-anastomotic stenoses.

iuffrida S, Morale W, L'Anfusa G, Puliatti D, Bisceglie P, Seminara G, Calcara G, Di Landro D, Malfa P.

PTX in Radiocephalfc lesions

TLPP 96% at 6 months


A
B
DEB

lume 9, Issue 22, November 2016>
I: 10.1016/j.jcin.2016.08.036

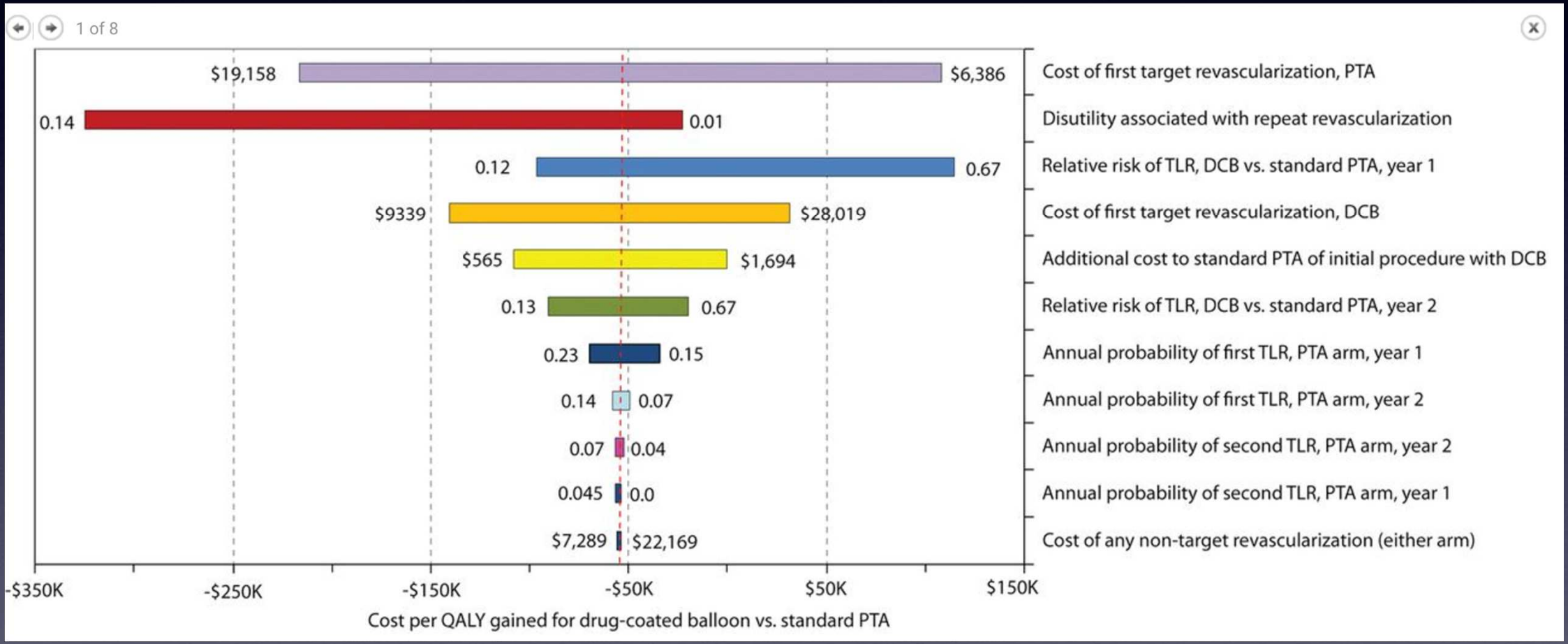
PDF Artic

ost-Effectiveness of Endovascular Femoropopliteal Intervention Using Drug-Coated alloons Versus Standard Percutaneous Transluminal Angioplasty

esults From the IN.PACT SFA II Trial

am C. Salisbury, Haiyan Li, Katherine R. Vilain, Michael R. Jaff, Peter A. Schneider, John R. Laird, David J. Cohen

Author + information


$19,158
$6,386
Cost of first target revascularization, PTA
0.14
0.01
Disutility associated with repeat revascularization
0.12
0.67
Relative risk of TLR, DCB vs. standard PTA, year 1
$9339
$28,019
Cost of first target revascularization, DCB
$565
$1,694
Additional cost to standard PTA of initial procedure with DCB
0.13
0.67
Relative risk of TLR, DCB vs. standard PTA, year 2
0.23
0.15
Annual probability of first TLR, PTA arm, year 1
0.14
0.07
Annual probability of first TLR, PTA arm, year 2
0.07
0.04
Annual probability of second TLR, PTA arm, year 2
0.045
0.0
Annual probability of second TLR, PTA arm, year 1
$7,289
$22,169
Cost of any non-target revascularization (either arm)
-$350K
-$250K
-$150K
-$50K
$50K
$150K
Cost per QALY gained for drug-coated balloon vs. standard PTA

Bottom Line

Drug coated technologies do seem to prolong interval between interventions

Is the cost worth it?

Will structure of health care reimbursement change the cost/value relationship?