Type of the Paper (Article)

Role of drug coated balloon angioplasty in treatment of recurrent dysfunctional arteriovenous fistulae for hemodialysis

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Received: 24 September, 2023 Reviewed: 19 October, 2023
Accepted: 25 October, 2023 Published online: 8 April, 2024

Abstract:

Introduction: It is generally agreed that patients receiving HD should have permanent access, such as a native AVF or AVG; however, it is still difficult in modern medicine to keep the AVF or AVG patent. Recent research indicates that 1-year patency rates range from 62% to 68%, while 2-year rates range from 38% to 56%.

Aim of the study: Evaluation of paclitaxel drug-coated balloon angioplasty for the treatment of recurrent dysfunctional arteriovenous fistulae (AVF) with respect to safety, therapeutic benefit, and patency results.

Subjects and Methods: Twenty patients with failed or failing AV fistulas were selected from treatment registers for a prospective case-series investigation.

Results: A fixed effect model was used for analysis as no significant heterogeneity was detected. The combined results suggested no statistically significant difference between groups regarding 3-month TLPP. forest plot of 3-month TLPP demonstrates a significant difference between groups In all, 10 studies evaluated the 6-month TLPP. After discovering substantial variability, we conducted the study using a random effect model. The combined result suggested no significant difference between groups regarding 6-month TLPP Since considerable variability was found, a random effect model was employed for the analysis. The combined result suggested no statistically significant difference between groups regarding 9-month TLPP

Conclusion: Clinical and duplex assessment at 3 and 6 months after DCB angioplasty demonstrated superiority in primary patency and intervention-free survival of the target lesion without evidence of increased side events.

Keywords: Drug-Coated Balloon Angioplasty, Recurrent Dysfunction, Arteriovenous Fistulae, Hemodialysis.

1. Introduction

When it comes to vascular access for hemodialysis, a mature "native" arteriovenous fistula (AVF) is preferable over prosthetic grafts or central venous catheters because of its higher performance and reduced complication rates. Although difficulties with AVFs are less common than with other vascular accesses, early & late AVF failure continue to be significant causes of illness for those on hemodialysis, as well as significant financial burdens on healthcare systems [1, 2].

Patients on hemodialysis face a significant obstacle every time they attempt to maintain their vascular access. Neointimal hyperplasia and stenoses usually develop. Stenosis prevents fistula maturation, interferes with function, and can induce thrombosis and loss of vascular access [3].

Recurrent stenoses (which may be a risk factor for recurrence) have been a problem requiring repeated interventions by traditional angioplasty, which has led to an increase in healthcare expenses and morbidity and mortality [4].

When it comes to treating coronary and peripheral artery stenoses, drug-coated balloons that release paclitaxel at the angioplasty site are at the top of the game. In light of this, drug-coated balloons are an appealing option for AVF stenosis [5].

Because of its ability to inhibit cell proliferation and neointimal hyperplasia, the anti-proliferative and antineoplastic agent paclitaxel is employed in drug-coated balloons (DCBs) [6].

DCBs have lately been the subject of several randomised trials looking at how they affect hemodialysis vascular access. However, sample sizes were often insufficient, and other research showed contradictory results [7].

This investigation sought to evaluate the efficacy, safety, and patency of paclitaxel DCB angioplasty in the management of recurrent dysfunctional arteriovenous fistulae (AVF).

2. Subjects and methods

2.1. Subjects

Twenty individuals with prior surgical PTA for the management of a failing or failed AV fistula were selected from treatment registries for this prospective case-series investigation.

Inclusion Criteria

Male or female patients over the age of 18 who can and will give informed consent and who will attend all protocol-mandated follow-up appointments; patients with an upper-limb arteriovenous fistula who have any of the clinical (e.g., abnormal thrill or bruit), pathophysiological, or hemodynamic abnormalities (e.g., failure to achieve adequate blood flow during dialysis) that necessitate angiographic imaging and treatment according to the Kidney Disease Outcomes. Dialysis access circuit with at least one severe (>50%) venous outflow stenosis, as determined by angiography. High venous pressure during dialysis, reduced blood circulation in the dialysis machine, increased bleeding with protracted hemostasis following dialysis, and loss of thrill or bruit were the most commonly observed clinical indicators of impending vascular access failure. Each patient enrolled in the trial has a stenosis or occlusion in an AVF that has already been treated with endovascular therapy (angioplasty ± a stent) in an attempt to rescue a failing or nonfunctioning fistula.

Exclusion Criteria

Pregnancy or planned pregnancy or breast feeding, Hypersensitivity to differences, Platelet inhibition intolerance, Hypercoagulable states, Active bleeding, or recent (<3 months) intracranial hemorrhage Infected AVF, arterial element as a cause of fistula failure, known hypersensitivity to the drug (paclitaxel), and patients with compliance difficulties.

2.2. Methods

Patient assessment

Full history taking; clinical examination (limb examination for assessment of arterial blood supply and exclusion of manifestations of ischemia; assessment of limb edema; presence or absence of thrill, bruit, signs of infection, or aneurysmal dilatation); and investigations (laboratory and radiological).

Technique

Access: radial or femoral access or outflow vein of the fistula. Using a 6F sheath under local anesthesia, then the introduction of a hydrophilic guide wire and supporting catheter. After crossing the lesion, plain old balloon angioplasty (POBA) is done as a pre-dilatation (vessel preparation) using a diameter of 5–6 mm or more and its length according to the length of the lesion using semi-complaint or non-complaint balloons. Preparation of the vessel with a plain balloon (under the age of 30 percent residual stenosis) before inflating a DCB. inflation of DCB of same diameter or 1 mm, is larger than that of a plain balloon, & inflation time is 3 minutes. The paclitaxel-coated balloon,

known as the Impact luminor (ivascular), served as the DCB. The paclitaxel dose in a urea vehicle is 3 g/mm2 of balloon surface.

A completion angiography is done to confirm technical success, and then the patient is assessed for clinical success. Technical success is confirmed by successful dilatation angiographically with no residual stenosis or residual stenosis less than 30% and absence of retrograde filling of the inflow artery. Clinical success is confirmed by adequate thrill, bruit, and hemodialysis.

2.3. Statistical analysis

The Statistical Package for the Social Sciences, version 20 for Windows, was used to do the analysis on the collected data. The results of the categorical data were presented as a percentage of the total, while the results of the continuous data were displayed as a mean (plus the standard deviation) or a median (plus the range). The Kolmogorov-Smirnov test was utilized to determine whether or not the data were distributed normally. This was done by measuring the distribution of the data.

3. Results

3.1. Literature search

The four databases used for the electronic search returned 449 references. We eliminated 229 duplicates, leaving 220 entries for title/abstract review. From the 30 publications that were deemed potentially relevant for full-text screening, only eleven met the inclusion requirements. No new articles were imported from the reference list after manual inspection. Eventually, eleven papers made it into the quantitative and qualitative reviews. Figure 1 is a flowchart depicting the methodology used to choose studies.

3.2. Risk of Bias within Studies

Inconsistencies in random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, insufficient outcome data, selective reporting, and other types of bias are illustrated in Figures 2 and 3. Except for the substantial risk of performance and detection bias demonstrated by the study conducted by Kitrou et al. (2015) that included trials exhibit either low or unclear risk across different parameters [8].

3.3. Meta-Analysis of Target Lesion Primary Patency

In all, five studies evaluated the three-month TLPP. A fixed effect model was used for analysis as no significant heterogeneity was detected (I2 = 23%, *P* = 0.27). The pooled rates were 86.3% (201/233) and 85.6% (201/232) for the PCB and CB groups, respectively. The combined OR and 95% CIs were 0.98 (0.57 to 1.67). The combined result suggested no statistically significant difference between groups regarding 3-month TLPP (Z = 0.09, *P* =.93).

One substantial variation between groups is seen in a 3-month TLPP forest plot.

Ten studies looked at the TLPP over its 6-month duration. A random effect model was used for analysis as significant heterogeneity was detected (I2 = 77%, *P* < 0.0001). The pooled rates were 72% (420/585) and 64% (369/576) for the PCB and CB groups, respectively. The combined OR and 95% CIs were 1.33 (0.71 to 2.49). There appeared to be no statistically significant differences between groups at 6 months for TLPP based on the combined results (Z = 0.88, *P* = 0.38).

In all, three studies evaluated the 9-month TLPP. After discovering substantial variability, we conducted the study using a random effect model (I2 = 69%, P = 0.04). The pooled rates were 48% (82/170) and 58% (99/171) for the PCB and CB groups, respectively. The combined OR and 95% CIs were 0.48 (0.13 to 1.82). Statistical analysis showed no significant group differences in TLPP at 9 months (Z = 1.07, *P* = 0.28).

3.4. Meta-Analysis of Technical Success

In all, eight studies evaluated the rates of technical success. Since no substantial heterogeneity was found, the data was analyzed using a fixed effect model (I2 = 46%, *P* = 0.13). The pooled rates were 97.4% (371/381) and 97.1% (368/379) for the PCB and CB groups, respectively. Overall, the odds ratio (OR) was 1.14 (95% CI: 0.84 to 2.71). There appeared to be no significant variance in the rate of technical success among groups, according to the overall data (Z = 0.29, *P* = 0.77).

3.5. Meta-Analysis of Mortality Rate

In all, six studies evaluated the all-cause mortality rates. A fixed effect model was used for analysis as no significant heterogeneity was detected (I2 = 0%, *P* = 0.50). The pooled rates were 6.9% (19/272) and 9.3% (24/257) for the PCB and CB groups, respectively. The combined OR & 95% CIs were 0.73 (0.40 to 1.35). The combined result suggested no significant difference between groups regarding mortality rate (Z = 0.99, *P* = 0.32) (**Tables 1-4**).

Table 1: Demographic data of the included studies.

Study	Year	Sample size		Age (years)		Sex (male/female)		BMI(Kg/m^2)	
		ITM group	ESPB group	ITM group	ESPB group	ITM group	ESPB group	ITM group	ESPB group
Baishya et al., [9]	2022	30	30	40.21+ 11.96	36.67± 12.76	19/11	21/9	22.60+3 .1	23.52+3.5 2
Hamed et al., [10]	2020	70	70	27.57 ± 6.11	27.97 ± 6.03	NR	NR	25.54 ± 4.74	25.71 ± 4.68
Kang et al., [11]	2019	27	27	36.5±1 0.5	32.9±1 2.4	20/7	12/15	23.8±2. 6	23.0±2.8
Kang et al., [12]	2021	29	30	37.4 ± 12.1	38.6 ± 13.1	13/16	18/12	23.8± 3.8	23.8 ±3.0

Data are presented by (mean ± SD) or event (total). NR= not reported, ITM= intrathecal morphine, and ESPB=erector spinae plane block

Table 2: The mean operating time, average anesthetic time, and average ASA physical status of patients in the included studies.

Study	Year	Duration of surgery		Duration of anesthesia		ASA physical status (I/II)	
		ITM	ESPB	ITM	ESPB	ITM	ESPB
Baishya et al., [9]	2022	127.17±3 2.24	122.03± 24.5	138.69±2 3.21	132.77+2 4.27	8(22)	5(25)
Hamed et al., [10]	2020	39.83±11 .97	39.69±1 1.8	NR	NR	NR	NR
Kang et al., [11]	2019	228±30	246±54	NR	NR	6(21)	7(20)
Kang et al., [12]	2021	210±36	222±24	270±36	282±24	3(26)	3(27)

Data are presented by (mean ± SD) or event (total). NR= not reported, ASA=American Society of Anesthesiologists.

Table 3. Research Characteristics (N = 681 PCB, and 658 CB).

First Author	Year	Country	No.	Age	Male	DM	HTN
Kitrou [8]	2015	Greece	20/19	64/57	60/70	20/35	15/15
Maleux [13]	2018	Luxemburg	33/31	69/67	73/58	NA	NA
Swinnen [14]	2019	Australia	68/60	65/64	62/62	56/56	NA
Trerotola [15]	2019	USA	141/144	64/61	62/59	58/65	94/97
Björkman [16]	2019	Finland	21/18	67/67	56/72	61/61	89/78
Lookstein [17]	2020	USA	170/160	66/65	66/63	63/69	91/94
Kim [18]	2020	Korea	20/19	61/64	60/47	80/79	NA
Karmota [19]	2020	Egypt	30/30	55/49	43/53	63/50	50/57
Therasse [20]	2021	Canada	60/60	55/49	83/83	62/72	87/82
Arabi [21]	2021	Saudi Arabia	12/11	69/67	42/55	92/73	100/91
Karunanithy [22]	2021	UK	106/106	67/64	63/58	55/43	NA

NA: Data not available

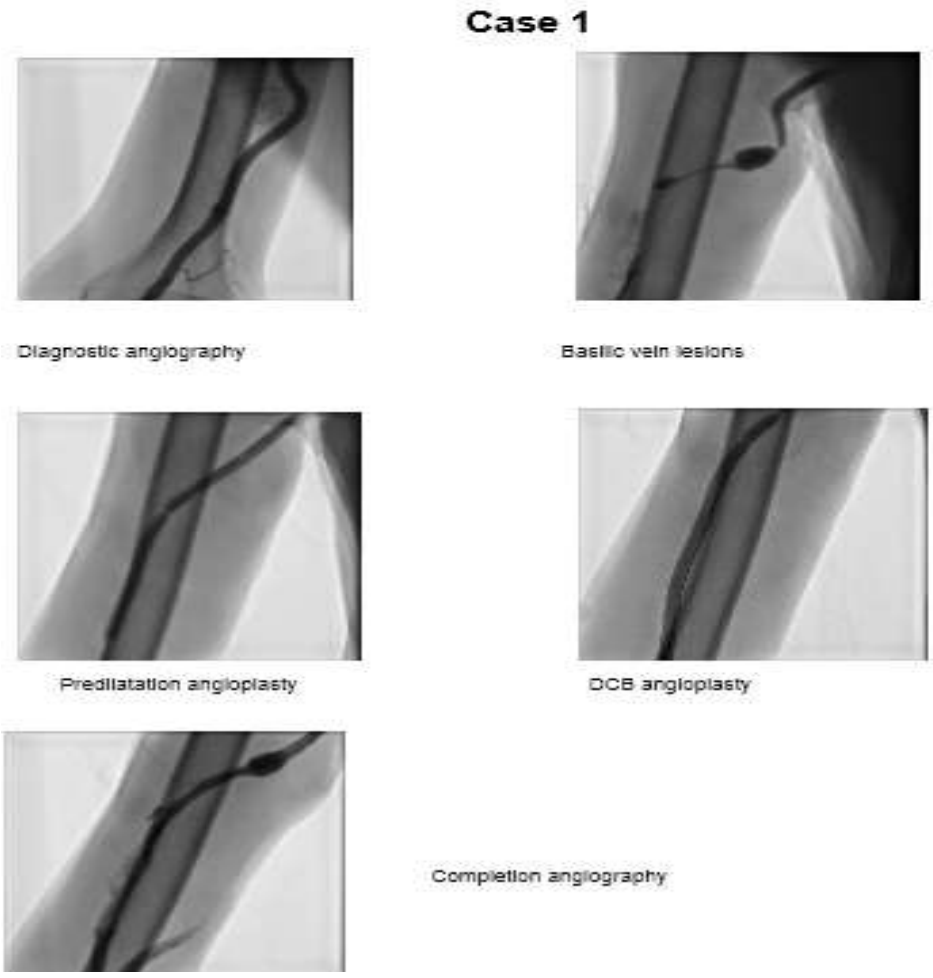
Table 4: Treatment Characteristics (N = 660 PCB, and 640 CB).

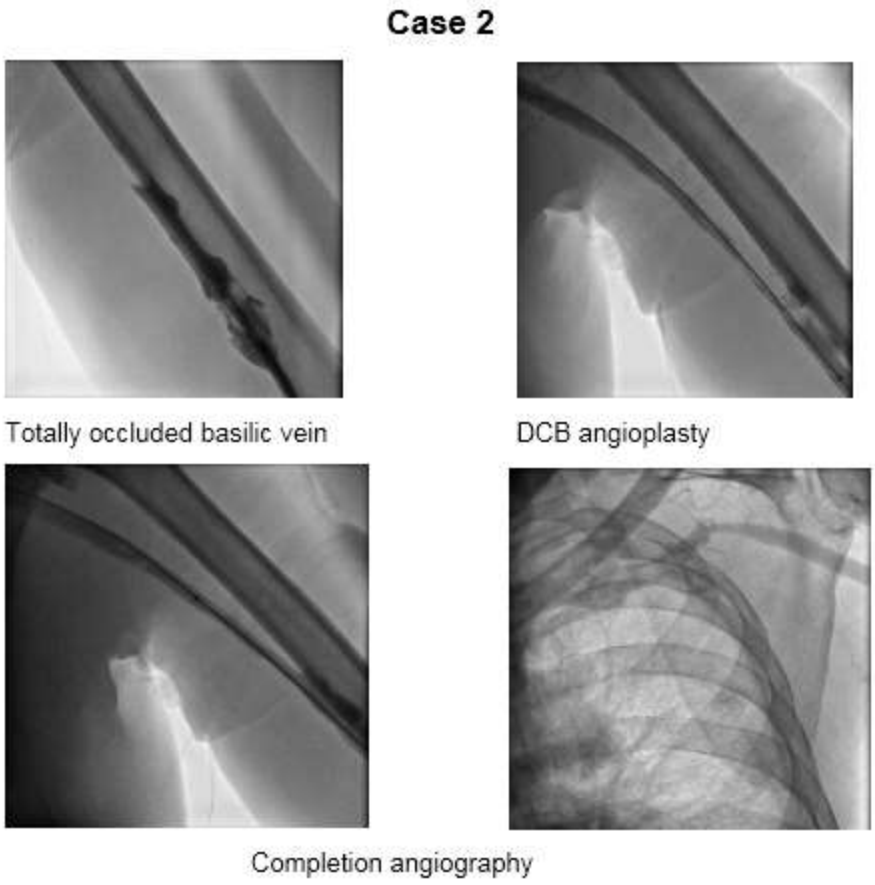
First Author	Year	Device Type	Inflation Time (Sec)
Kitrou [8]	2015	PCB: IN. PACT Admiral, Medtronic (3 mg/mm^2) CB: HPB	90
Maleux [13]	2018	PCB: IN. PACT Admiral, Invatec/Medtronic (dose unspecified) CB: Admiral Extreme, Invatec/Medtronic	NA
Swinnen [14]	2019	PCB: IN. PACT Admiral/Pacific, Medtronic (3 mg/mm^2) CB: Uncoated balloon of the operator's choice	120
Trerotola [15]	2019	PCB: Lutonix 035, Bard (2 mg/mm^2) CB: Uncoated balloon of similar design	NA
Björkman [16]	2019	PCB: IN. PACT Admiral, Medtronic (3.5 mg/mm^2) CB: Unspecified	90
Lookstein [17]	2020	PCB: IN. PACT Admiral, Medtronic (3.5 mg/mm^2) CB: Unspecified	NA

Kim [18]	2020	PCB: IN. PACT Admiral, Medtronic (dose unspecified) CB: Mustang, Boston Scientific	120
Karmota [19]	2020	PCB: Lutonix 035, Bard (dose unspecified) Control: Unspecified	180
Therasse [20]	2021	PCB: Passeo-18 Lux, Biotronik (3 mg/mm^2) CB: Uncoated balloon of similar design	60
Arabi [21]	2021	PCB: Lutonix 035, Bard (2 mg/mm^2) Control: Unspecified	120
Karunanithy [22]	2021	PCB: Lutonix 035, Bard (2 mg/mm^2) Control: Ultraverse, Bard	NA

NA: Data not available

3.6. Case presentation





4. Discussion

The demographics of our study population were as follows: The mean patient age was 49.4 ± 17; 14/20 (70%) patients were male, 6/20 (30%) were female; 30% were cardiac, 50% were hypertensive, and 10% were diabetic. 60% were brachiocephalic fistulas, and 15% were AVGs. At study enrollment, the average age of the fistula was 1.5 years (range 6 months–11 years).

This is similar to patients` criteria in a comparative study between conventional and DCB angioplasty in recurrent radio-cephalic arteriovenous fistulas done by Haave et al. (2019) on thirty-six patients who had previously undergone PTA and were subsequently re-intervened (13 PTAs and 13 DCBs) at the same physical coordinates [23].

If drug-coated balloon PTA was unsuccessful or rebound occurred, plain balloon post-dilation was performed.

As opposed to this research, DCB angioplasty was the initial procedure in the studies conducted by Katsanos et al. (2012) and Kitrou et al. (2015), where in nearly half of the

instances, the angiographic finding was insufficient; therefore, the researchers reopened the stenosis entirely by using a PTA balloon catheter and high pressure [8, 24].

Technical success was almost the same in all DCB AVF hemodialysis angioplasty studies, defined as residual stenosis less than 30%.

In relation to clinical success evaluation, the main prognostic factors used in our study were adequate thrill and bruit, and the most important and reliable was adequate hemodialysis.

Studies on DCB angioplasty on AVFs vary widely between those three previously mentioned parameters for clinical follow-up.

For example, three dialysis sessions with normal dialysis parameters were considered clinically successful following angioplasty in the study by Moreno-Sánchez et al., (2020) [25].

The term "fistula patency" refers to a fistula that has been successfully used for multiple dialysis treatments without requiring additional endovascular or surgical repair.

Access survival (primary patency) was defined as the time from the placement of the access and the earliest of either the measurement of patency or the earliest of any intervention to maintain or restore patency or prevent access thrombosis [26].

In this particular research, the rate of primary patency was shown to be 80% after three months and 65% after six months.

The duration of assisted primary patency (access survival without thrombosis) was defined as the time that passed between the placement of the access and the measurement of patency, regardless of the number of intervening manipulations (surgical or endovascular interventions) used to keep the access open and functional. From the moment an access was placed until the moment patency was evaluated, this time frame was calculated [26].

In our study, two cases of failing fistulae needed reintervention by conventional angioplasty, and they have been patented up until now.

According to other studies testing the effectiveness and patency of DCB angioplasty on AVFs, most of the results recommended the use of DCB for prolonged patency of AVFs.

The first randomized trial was published in 2012, Katsanos et al. revealed that in a randomized control trial (RCT) with 20 patients in each group, those treated with DCB had a significantly higher proportion of stenosis-free patients six months following therapy compared

to those treated with PTA (70% vs. 25%, $p < 0.01$) [24].

In our study, target lesions primary patency in AVFs and AVGs at three months was 80% and at 6 months was 65%.

These patency rates are higher than those of the same AVFs and AVGs since previous plain angioplasty (70% patency after three months and 30% after six months).

It was found that all three AVGs included in this study reoccluded and failed (two of them after a 3-month follow-up and the remaining one after a 6-month follow-up).

This result goes along with a previous study revealed that aggressive neointimal hyperplasia following vascular damage, most commonly at the venous anastomosis, is a major contributor to the high incidence of early AVG restenosis following angioplasty [27].

Regarding safety and complications following DCB angioplasty, there were no adverse events in our study directly related to DCB use.

One patient died, but due to cardiac arrest at the 3-month follow-up, central venous occlusion occurs in only 2 cases, and infection occurs in one AVG case, so it had to be removed.

At 30 days, 95% of patients were free from local or systemic adverse events thanks to the DCBs; this dropped to 80% at 6 months for reasons unrelated to the DCBs.

Concerns have been expressed for the dialysis population due to the higher mortality risk seen with DCBs in peripheral artery disease. So far, there is no evidence of a comparable signal in the hemodialysis patient population.

The results of a meta-analysis of eight studies found that neither DCBs nor traditional balloons showed any distinguishable differences in fatality rates (11.2%; RR, 1.26; 95% CI, 0.85 to 1.89; $p = 0.25$; I2 = 0%) [28].

Conclusion

There was no indication of an increase in adverse events after DCB angioplasty, and clinical and duplex assessment at 3 and 6 months demonstrated superiority in primary patency plus target lesion survival without further treatment.

DCB angioplasty carries better extended patency when compared to conventional percutaneous angioplasty, especially in recurrent AVF stenoses and occlusions. DCB treatment for failing and failed fistulas should be studied further to demonstrate its efficacy

and safety, ideally over a longer follow-up period and in larger or more varied populations.

Funding: This study is not funded.

Conflicts of Interest: All authors declare they have no conflicts of interest.

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