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Original research

Comparison of clinical results between angioplasty balloon and venous angioplasty stent in dialysis dependent patients with upper extremity swelling due to venous hypertension following vascular access

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Abstract

Comparing the clinical outcomes between the endovascular balloon and stent methods in edema and upper extremity venous hypertension proceeding treatment via vascular access is an important subject to find a practical approach of modifying dialysis side effects, improve the quality of medical care, and increase the life span of patients. From 2016 to 2018, 41 dialysis patients with central vein stenosis in Golestan Hospital of Ahvaz were randomly allocated into two groups: balloon angioplasty (24 patients) and stent angioplasty (17 patients). Patients were closely monitored in the 1st, 3rd, and 6th months after angioplasty. Both groups underwent dialysis the following year. In this research, 35 patients had upper left limb involvement (85.4%). The most common location of venous stenosis was the left brachiocephalic vein (innominate vein). Inflammation was mainly in the forearm and arm regions. There was a significant relationship in the therapeutic effect for reducing inflammation in each group ($p<0.05$), but the most remedial effects occurred in the first month after treatment. The primary patency and inflammation reduction in the 3rd and 6th month had been more in stent angiography. The difference between these two methods did not prove significant over a year according to their dialysis procedure. The present study results showed that the utilization of stent angioplasty is preferred over balloon angioplasty in the long term in patients suffering from edema and hypertension.

Keywords: Dialysis, Angioplasty, Stent, Vein Stenosis, Vascular catheters

Introduction

Hemodialysis is a standard treatment for patients with kidney failure and the best alternative for kidney function. The better the treatment administered, the better the quality of life [1]. Nowadays, more than 1.5 million patients with kidney failure highly depend on hemodialysis, peritoneal dialysis, and kidney transplant [2]. One of the essential factors in hemodialysis is vascular accessibility; central venous stenosis can potentially hinder this access by obstructing the vessels [3] or initiating venous hypertension and causing extremity edema to necessitate access ligation for symptom relief. There are three ways of gaining vascular access: arteriovenous fistula, graft, and central venous catheter [4-6].

Despite the importance of vascular accessibility for patients in need of hemodialysis, only a few veins remain available over time. In the USA, it was reported that just about 50% of the veins in patients with kidney failure are available for dialysis for the next three years, and a substantial amount of money is required to solve this problem (> $1 million per year, increasing annually by 6%) [7]. Upper extremity edema (mild to severe) due to venous hypertension has been reported and is a consequence of insufficiency and obstruction of the intravenous system [8].

There are different ways of treating vascular obstruction and reducing its side effects in patients who need hemodialysis; angioplasty with balloon and stent are the most common methods [9]. Researchers are always searching for better ways with minimum side effects [10]. Some previous studies recommend

using stent angioplasty [11], while in other researches, the use of balloon angioplasty was suggested due to its cost-effectiveness and patient satisfaction rather than stent angioplasty [12]. There has been little research on the comparison of stent and balloon angioplasty methods; hence, this study was designed to compare balloon and stent angioplasty in patients with swelling in the upper extremity due to venous hypertension in upper organs, driven by the importance of vascular access in patients who require dialysis and to increase the quality of life in patients undergoing hemodialysis in Khuzestan province.

Materials and Methods

Study design

This prospective clinical trial was performed on dialysis-dependent patients with upper extremity swelling referred to the hybrid operating vascular surgery room of Golestan hospital in affiliation with Ahwaz University of Medical Sciences from 2016 to 2018. A comprehensive history was taken from each patient, and the data obtained was registered in the relevant code sheets. After matching the data with patients' age, the next step involved the random categorization of patients into two distinct groups. To follow the double-blind study format, none of the patients were given details of the allotted category. Furthermore, the researcher examined patients' clinical results without prior knowledge of the kind of treatment each patient was receiving.

Participants

According to the Cochran formula, the sample size attained about 30 participants (15 patients in each group). The patients' inclusion criteria to enter the study included clinical signs of venous hypertension in the upper extremity with vascular access, upper organ swelling, wound, skin pigmentation, and bleeding after dialysis and age between 20 to 85. The exclusion criteria that disqualified the patients for the study were lack of consciousness and psychological disorders. In this study, 47 dialysis patients qualified for angioplasty were randomly divided into balloon angioplasty (24 patients) and stent angioplasty (17 patients). Angioplasty could not be performed in 6 patients.

Intervention and follow-up

A thorough and organized history was obtained from the patients who met the criteria to participate in the study, and they were categorized into two different groups in terms of age. Additionally, they received a particular written consent form to enlighten them on the objectives of the research. Venography was done by a DSA angiography machine (Ziem). Patients were anesthetized in a hybrid surgery room for vascular access venography of the upper extremity. After the central vein's anatomic investigation and certifying the location of the obstruction, a proper stent was used in the stent angioplasty group. The high-pressure vein balloons were used based on the site and degree of obstruction in the balloon angioplasty group. Also, patients were monitored by ECG and pulse oximeter during the procedure. They were closely monitored for the 1st, 3rd, and 6th months after angioplasty. Both groups underwent dialysis after a year from when they were discharged from the hospital.

Data collection

Data was gathered from two sources: 1) Questionnaires were containing patient demographic information. Demographic data were obtained by interviewing and checking patient records. 2) The researcher's checklist included the date of dialysis onset, location of swelling in the upper extremity, vascular access type, catheter location and type, venography date, organ size before and after of angioplasty, location of the obstruction, and venography types (stent or balloon).

Statistical analysis

The data attained in the present study were analyzed in SPSS v.22 using descriptive and inferential indices through a repeated measurement method and a one-way ANOVA test. The Wilcoxon Signed-rank test was used to compare population mean ranks. Also, the chi-square test and paired T-test were employed for the comparison between the different groups; a significance level was considered when P-value <0.05.

Ethical considerations

This study was performed under the guidelines and regulations of the ethical committee and research committee of Golestan Hospital in Ahvaz province. Before entering the study, all the patients were informed about the process and research objectives and were requested to fill in a written consent form subjectively. All the study procedures conducted were

consistent with the Declaration of Helsinki, and the medical files of the patients were kept confidential. The research team handled this study's expenses, and no additional costs were requested from the patients. Furthermore, all patients had follow-up for treatment control. This research was approved by the Ahwaz University of Medical Sciences' ethical committee issued with code number: IR.AJUMS.REC.1396.1110.

Results

Demographic properties

In this study, 47 patients were chosen randomly, out of which 6 (13%) were excluded due to vascular obstruction. The remaining 41 patients constituted 27 women (65.9%) and 14 men (34.1%) with an average age of 61.4 (range: 37 – 85) years. The average age of women was 61.6, and the average age of men was 62.8 years, with no significant difference between the two groups in terms of age or gender.

Periprocedural variables

Swelling of the upper organ: About 35 patients (85.4%) with left upper extremity swelling had venous hypertension. Six patients (14.6%) had right upper extremity swelling and hypertension (Table 1). We observed statistically significant differences in the treatment between the two groups (P≤0.05).

Inflammation of limb: swelling was mainly found in the lower part of the upper extremity (wrist, forearm, and arm). About 25% of edema was found in the shoulder, neck, and upper thorax (Table 1).

Venography: according to the endovascular demography performed to investigate the vascular obstruction location, the maximum obstruction was in the left Brachiocephalic (BC) vein and then the right BC vein. There was also obstruction in the superior vena cava (SVC) or subclavian vein (88%). About 15% had superior vena cava and subclavian obstruction simultaneously (Table 1).

Outcome

Recovery after the 1st, 3rd, and 6th months is shown in Figures 1 and 2. After a month of treatment, the mean amount of inflammation in the arm and forearm has decreased significantly (both in balloon and stent therapy). After the 3rd and 6th month, both stent and balloon groups depicted a decrement in swelling. However, swelling reduction persisted for a longer time and was more effective in patients who underwent stent angiography than patients with balloon angiography.

Based on our results, all patients who had endovascular treatment were monitored over a year according to their dialysis procedure. There were no cases of mortality in our study, and all patients completed the follow-up. Although 24 cases of balloon and 17 cases of stent demonstrated successful and significant results (P ≤0.05), the difference between these two methods did not prove substantial (P = 0.993). In the evaluation of dialysis, relative dialysis indicates almost adequate dialysis that requires a high speed of the device or longer duration required for dialysis.

Discussion

Central vein stenosis or occlusion resulting in considerable edema of the arm with the inability of vascular access to drain is a frequent side effect of chronic hemodialysis. Percutaneous interventions such as percutaneous transluminal angioplasty (PTA)/balloon angioplasty and percutaneous transluminal stenting (PTS)/stent angioplasty are preferred over surgical intervention since surgical repair of these central veins can be challenging [13]. In the present study, 47 patients were investigated, from which 6 (13%) were excluded due to the lack of venous cannulation. These 41 patients were randomly divided into 14 men (34.1%) and 27 women (65.9%). In 2015, a retrospective study was performed with 45 patients, and in 2013, another retrospective study was done on stent and balloon angioplasty with 24 patients. These studies have similarities with our research in terms of the sample size [14, 15]. Also, their patients' average age was 57.5, which was approximately equal to the average age of our participants [61.6].

Two key factors are described to cause stenosis of the central vein during dialysis: temporary catheterization of central vein for hemodialysis (mainly when the subclavian vein is accessed) [16-19] and the high flow state and increased turbulence induced by the creation of an arteriovenous shunt [20, 21]. Hemodialysis access maintenance may be complicated by increasing arterio-venous access pressure in the early stages of central vein stenosis [3]. Generation of significant local morbidity in the extremity, chest, neck, and even face via swelling also adds to the complication.

Table 1. Patient demographics and periprocedural variables

Variable		Count within vein therapy % (n)			P-value
		Balloon n=24	**Stent** n=17	**Total** n=41	
Demographic					
Gender	Male	33.3 (8)	35.3 (6)	34.1 (14)	0.578
	Female	66.7 (16)	64.7 (11)	65.9 (27)	
Indication for intervention					
Swelling upper organ	Right	12.5 (3)	17.6 (3)	14.6 (6)	
	Left	87.5 (21)	82.4 (14)	85.4 (35)	
Inflammation of limb	Forearm	79.2 (19)	70.6% (12)	75.6 (31)	
	Neck	20.8 (5)	29.4 (5)	24.4 (10)	
Venography	Brachiocephalic	70.8 (17)	76.5 (13)	73.2 (30)	
	Superior vena cava	20.8 (5)	0 (0)	23.5 (4)	
	Both	8.3 (2)	23.5 (4)	14.6 (6)	
Used Device	Fistula	62.5 (15)	58.8 (10)	61 (25)	0.533
	Graft	37.5 (9)	41.2 (7)	39 (16)	

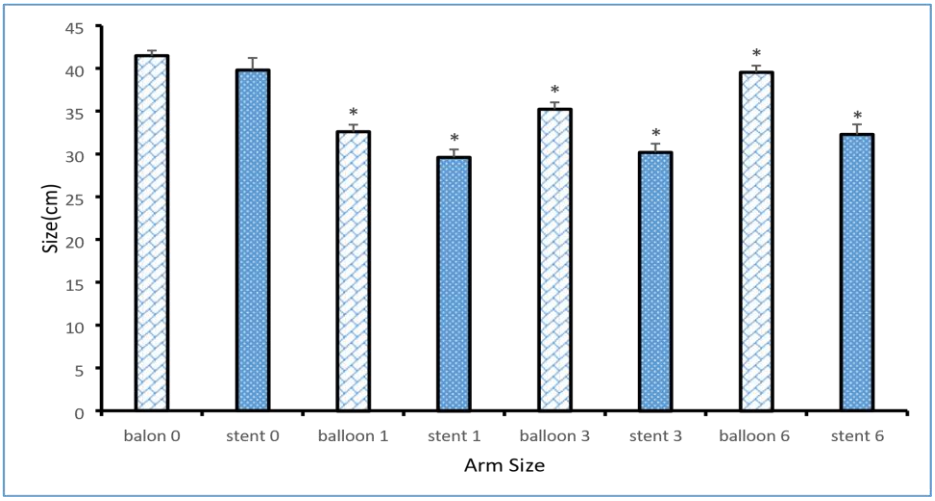

Figure 1. Arm size (inflammation value) in dialysis cases. Balloon 0: at the beginning of the trial. Balloon 1: 1 month after treatment. Balloon 3: 3 months after treatment. Balloon 6: 6 months after treatment. Results are presented as mean ± SD; P ≤0.05.

Our findings demonstrated that 35 patients (out of 41 patients) had left upper extremity complications (85.4%), and 6 of them had right upper extremity complications (14.6%). This is proportionally similar to another study in which 22 patients (out of 27 patients) had left upper extremity complications (81.5%), and 5 had right upper extremity complications (18.5%). Chandler et al. also reported 7

and 5 cases with complications in the right and left upper organs, respectively. More recently, Haskal showed that in balloon and stent angioplasty, the right upper extremities were more involved with complications [12].

Kang et al., in a recent retrospective study in 2016, demonstrated that the stent method was by far more effective than a balloon in a large number of patients [27] which was consistent with the superiority of stenting in our study. Also, Dukkipati et al. researched

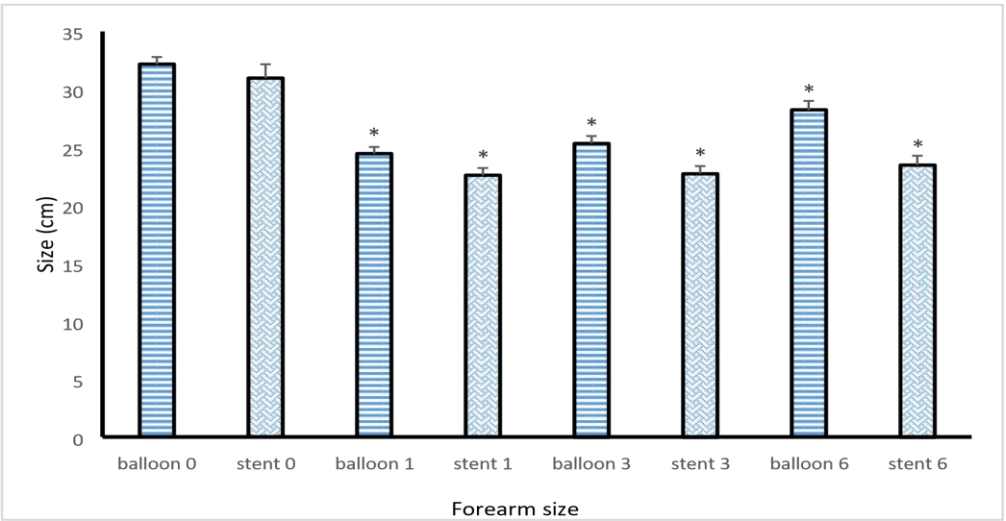

Figure 2. Forearm size (inflammation value) in dialysis cases. Balloon 0: at the beginning of the trial. Balloon 1: 1 month after treatment. Balloon 3: 3 months after treatment. Balloon 6: 6 months after treatment. Results are presented as mean ±SD; P≤0.05.

Other than ligation of the fistula and forfeiting extremity access, open surgical angioplasty was the only management strategy available before the invention of percutaneous therapy. Although open methods have proven to be reasonably durable with 1-year primary patency of 80%-86% [22, 23], patients sustain significant morbidity due to chest embedded lesions. Therefore, the employment of percutaneous methods was initiated to treat central venous stenosis in the mid-1980s [24].

A decade ago, the overlapping of two or more second-generation drug-eluting stent and a single long drug-eluting stent was assessed in patients with coronary obstruction hospitalized in Imam Khomeini Hospital in Ahvaz province. Raadi et al. reported that their results did not significantly differ between the two groups [25].

Retrospective research by Mital on upper extremity hypertension on 37 patients for ten years illustrated that the main vein obstruction was seen in brachiocephalic and radio-cephalic veins. Moreover, Yadav et al. depicted that the most vulnerable locations for obstruction in patients who had balloon angioplasty were brachiocephalic and axillary veins [26].

with 45 participants and concluded that stent angioplasty helped keep the vein open rather than balloon angioplasty. In contrast, in another research by Shi et al., in 24 patients, no significant differences were observed between the two treatment methods (stent and balloon) [14].

Haskal et al. also carried out a study with 190 patients and found that the side effects in stent angioplasty were more than balloon angioplasty (51% compared with 21%). It is interesting to note that in this study, the use of balloon angioplasty was highly recommended [12].

Ozyer et al. conducted a study to assess the long-term effect of angioplasty in dialysis patients (126 hemodialysis patients) to treat venous obstruction in Turkey. Their results showed that vein obstruction could be treated effectively via stent angioplasty in hemodialysis patients, and it also extends the life span of patients. Hence, stent utilization should be considered [28].

Also, Sprouse et al. evaluated the stent angioplasty in hemodialysis patients with swelling in upper organs. The results depicted that the main reason for vein obstruction was hemodialysis (87%), and the remaining was because of central vein catheterization.

Finally, they reported that vein obstruction was an inevitable problem which the vein angioplasty could ease. However, other treatments and methods are needed to reduce this problem in the long term, along with angioplasty [29].

In this research, we have highlighted that the two groups, which were treated by balloon angioplasty and stent angioplasty to control the swelling in the mid-forearm and arm (measured by caliper and standard metrics), experienced significant reduction in swelling in the first months. Although an equal efficacy was observed in the first three months after the intervention, the initial patency's longevity was higher in stenting (about 95-100%) compared to balloon angioplasty (70-90%) within the same period. Following the same trend, the persistence of initial patency for stent (75-89%) and balloon (22-51%) angiographies reduced consistently after six months. This reduction in patency was among the cause of stenosis regeneration at six months' post-therapy and thus, contributed to the recurrence of the basic problem of edema, which was more frequent in patients with balloon angioplasty. All in all, initial patency in stent angioplasty was much better than balloon angioplasty in the 3rd and 6th months after treatment with a significant difference, while the difference after the 6th month demonstrated no significance between the two groups of treatment.

In 2007, Bakken et al. in the USA treated patients with central vein obstruction with stent (26 patient) and balloon (47 patient) therapy. The primary rate of vein patency in both groups after one month was 76%, and after 12 months, 29% and 21% for balloon and stent, respectively. Balloon therapy was reported as the better method for curing central vein obstruction, while stent therapy did not increase vascular access longevity [30].

Angioplasty alone may serve as a reasonable option for treating central venous lesions, and stents may only assist angioplasty by limiting the elastic recoil present in involved veins (not damaged and dissected intravascular tissues) and provide intravascular support to neutralize extrinsic compression (31). Central venous lesions described as having high elastic recoil obey the rule mentioned above and, hence show unsatisfactory results with PTA alone [31]. Therefore, it is not a surprise that reports concerning PTA as the only management option would lower patency rates. We observed some discrepancies in the obstructed central vein's patency rates managed by PTS compared to previous findings. We believe that these variations may have risen from different PTS protocols, types of stents, study populations, age of access, access thrombosis at the time of intervention, and veins treated [31-35].

In conclusion, both endovascular balloon angioplasty (PTA) and stent angioplasty had significant therapeutic effects for edema and hypertension treatment due to central vein obstruction caused by vascular access. However, the long-term impact of stent angioplasty (3rd to 6th month) and its initial patency was more satisfactory than balloon therapy.

Author contribution

All authors contributed equally and approved the final version of the manuscript.

Conflict of Interest

The authors have no conflicts of interest to declare.

Ethical declaration

This research design was approved by the Ahwaz University of Medical Sciences' ethical committee issued with code number: IR.AJUMS.REC.1396.1110.

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