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# Bovine pericardial patch: A good alternative in femoral angioplasty

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## ABSTRACT

**Objective:** Bovine pericardial patch (BPP) is currently used in femoral angioplasty as an alternative for autologous vein patch (AVP), but studies comparing the results of the two methods are scarce. In this retrospective study, we aimed to discover the differences between BPP and AVP closure in long-term durability.

**Methods:** This study consisted of all femoral endarterectomies with BPP closure performed in Helsinki University Hospital from January 1, 2014, to December 31, 2017. For comparison, the same number of consecutive patients who underwent femoral endarterectomy with AVP closure from January 1, 2014, to October 16, 2016, were reviewed. Follow-up ended December 31, 2020. The mean follow-up was 19 months (range, 0-74 months) in the BPP group and 22 months (range, 0-79 months) in the AVP group. The primary endpoint was primary patency. Secondary endpoints were restenosis at patch site detected by imaging or perioperatively, patch rupture, and deep surgical wound infection. Propensity score analysis was performed for adjustment of differences between the AVP and BPP groups.

**Results:** Overall primary patency was superior in the AVP group compared with the BPP group: at 1 year, 96.5% vs 85.0% and at 5 years, 83.0% vs 72.3% ( $P = .04$ ). In propensity score-matched pairs ( $n = 92$ ), no difference was found between the groups in primary patency: 95.7% and 95.7% at 1 year and 92.5% and 78.6% at 5 years ( $P = .861$ ) or in freedom from restenosis: 100% and 100% at 1 year and 89.1% and 84.0% at 5 years ( $P = .057$ ). Deep wound infections occurred slightly more often after BPP closure (8%) than after AVP closure (4%), but the difference was not statistically significant ( $P = .144$ ). There were no patch ruptures in the BPP group, but in the AVP group, there were five ruptures (3.5%) ( $P = .024$ ).

**Conclusions:** BPP is compatible to AVP in femoral endarterectomy in patency and can be regarded as the safer choice considering the risk of patch rupture. (*J Vasc Surg* 2023;77:225-30.)

**Keywords:** Bovine pericardial patch; Femoral endarterectomy; Patch angioplasty

Femoral endarterectomy is one of the most common procedures in vascular surgery. Even in this constantly evolving endovascular era, surgical revascularization with long-term patency results of 90% to 96%<sup>1-3</sup> has held its position as the standard treatment of atherosclerosis in the femoral bifurcation.<sup>4</sup>

Endarterectomy is often extended beyond the femoral bifurcation, and profundoplasty may also be needed. Patch closure is recommended to avoid stenosis resulting from direct suturing. Autologous vein patch (AVP) is

traditionally used in closure, but it is not always available. Also, because the great saphenous vein (GSV) is the vein most often used, it may be wise to preserve it for a possible later bypass. Furthermore, vein patch may be sheer, which may increase the risk of postoperative patch rupture.

Prosthetic patches are available, but they are reluctantly used in the groin area because of the relatively high (9%-19%) risk of infection after surgery in the femoral region.<sup>5-7</sup> Also, if a wound with a prosthetic patch is infected, redo surgery is required, including the removal of the infected patch.<sup>8</sup> This can be an extensive procedure requiring prolonged wound care afterwards. Overall, the ramifications of prosthetic patch infections and managing them may cause the patient significant morbidity and possibly limb loss and mortality.<sup>9</sup>

Bovine pericardial patch (BPP) has been used as an alternative for vein patch in carotid surgery where vein patch blow-outs have been reported,<sup>10,11</sup> and promising results using BPP in terms of durability, morbidity, and mortality have been presented.<sup>12,13</sup> Vein patch ruptures have also been reported in the inguinal region,<sup>14</sup> making the BPP a tempting alternative for femoral angioplasty. In transplantation surgery<sup>15</sup> and in aortic prosthesis infections,<sup>16,17</sup> pericardial patch has also been successfully used.

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Although surgical endarterectomy is the gold standard for common femoral artery atherosclerosis, studies comparing vein and bovine patch angioplasties in the femoral artery are scarce. Similar patency results have been reported when repairing femoral arteriotomies in infected fields.<sup>18</sup> Furthermore, no difference in postoperative wound infections was found in a retrospective study by Derksen et al<sup>19</sup>; rather redo surgery and wound drain were found as risk factors for infection.

In Helsinki University Hospital (HUU), approximately 200 procedures including femoral endarterectomy with patch closure are performed every year. To minimize the risk for postoperative infection, prophylactic antibiotics are administered, and our surgical technique includes oblique incision in the groin.<sup>20</sup>

The advancements in endovascular surgery has led to the increasing number of hybrid procedures including femoral endarterectomy and inflow or outflow percutaneous transluminal angioplasty. BPP provides a tempting alternative platform for the endovascular treatment performed usually after the femoral endarterectomy, for the pericardial patch is sturdier for puncture and access than the vein patch or the endarterectomized arterial wall.

In 2014, nearly all the femoral patch closures were performed with BPP in HUU until there were a couple of cases with unfortunate restenosis and reoperations. This led to the termination of using BPP and returning to the use of AVP.

This retrospective study was launched to discover whether BPP and AVP differ in terms of immediate postoperative complications and long-term durability.

## METHODS

This retrospective study consists of all femoral endarterectomies with bovine pericardial patch closure (PeriGuard Supple or Xenosure) performed in HUU from January 1, 2014, to December 31, 2017. For comparison, consecutive patients undergoing femoral endarterectomy with AVP closure from January 1, 2014, to October 16, 2016, were reviewed. Prospectively maintained vascular registry and prosthesis registry provided patient data for our retrospective analysis. To improve the comparability of the two groups, a propensity score analysis was performed. The study protocol was approved by the Institutional Review board of HUU (Department of Surgery).

Primary endpoint in the study was primary patency, defined as the uninterrupted patency time from the patch angioplasty, according to the ad hoc committee's reporting standards for reports dealing with lower extremity ischemia.<sup>21</sup>

Secondary endpoints were restenosis at the patch site, patch rupture, and deep surgical wound infection. Restenosis was defined as stenosis at patch site over 50%

## ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective
- **Key Findings:** In 92 propensity score-matched pairs, no difference was found between bovine pericardial patch (BPP) compared with autologous vein patch (AVP) in primary patency: 95.7% and 95.7% at 1 year and 92.5% and 78.6% at 5 years ( $P = .861$ ). None of the BPPs ruptured, whereas 3.5% of the AVPs ( $n = 5$ ) ruptured.
- **Take Home Message:** BPP is the safer choice in femoral endarterectomy compared with AVP.

detected either by ultrasound, computed tomography, or magnetic resonance imaging or during reoperation. The patency endpoint was set as the date of primary operation if there were no postoperative imaging or reoperations.

Criterion for deep infection was infection extending to femoral arteries. Follow-up was extended until December 31, 2020.

Our routine surveillance is based on clinical follow-up. For patients operated due to ischemic tissue loss and rest pain, the protocol is a visit at our vascular outpatient clinic including ankle-brachial index and toe pressure measurements at 1 month postoperatively. Further visits are scheduled individually. For patients with tissue loss, follow-up is extended until the wound has healed or nearly healed. For patients treated for claudication, follow-up is determined individually and set at 1 month if considered necessary. In case of reoccurring symptoms or suspicion of failing patency, additional imaging is performed.

**Statistical analysis.** Statistical analyses were performed using SPSS statistical software v. 24.0 (IBM Corporation, Armonk, NY). The normal distribution of continuous data was confirmed with the Shapiro-Wilk test. The  $\chi^2$  test, Fischer exact test, and Mann-Whitney  $U$  test were used for univariate analysis. Kaplan-Meier analysis and log rank test were applied to estimate the time-dependent outcome of patency and restenosis. Cox proportional hazards method was applied for risk estimation of endpoints adjusted by the variables with  $P < .20$  in the univariate analysis. To account for differences in pretreatment covariates between the AVP and BPP groups, a propensity score was calculated with logistic regression. In the regression model, we included known risk factors for atherosclerosis (age, gender, diabetes, dyslipidemia, smoking habit, indication of surgery, type of revascularization, inguinal redo surgery, and urgent surgery) as well as variables with  $P < .50$  listed in [Tables I and II](#). One-to-one propensity score matching between study groups was done according to less than 0.02 difference in the propensity score between each

**Table I.** Clinical data of the patients as related to the treatment groups

Clinical characteristics	BPP group (n = 144)	AVP group (n = 144)	P
Age, years <sup>a</sup>	74 (30-96)	72 (30-95)	.061
Male gender <sup>a</sup>	72 (50)	102 (71)	<.001
Diabetes mellitus <sup>a</sup>	57 (40)	53 (37)	.628
Coronary arterial disease	64 (44)	62 (43)	.812
Dyslipidemia <sup>a</sup>	121 (86)	104 (72)	.109
Hypertension	113 (79)	111 (77)	.777
Chronic obstructive pulmonary disease	29 (20)	29 (20)	1.0
Cerebrovascular disease	31 (22)	29 (15)	.306
Renal insufficiency requiring dialysis	3 (2)	2 (1)	.652
Smoking habit <sup>a</sup>	55 (38)	59 (41)	.384
Rheumatic disease	11 (8)	7 (5)	.323
BMI, kg/cm <sup>2</sup>	25 (16-39)	26 (17-40)	.435

AVP, Autologous vein patch; BMI, body mass index; BPP, bovine pericardial patch.  
Data are presented as number (%) or mean (range).  
<sup>a</sup>Variable included in the regression model for estimation of the propensity score.

**Table II.** Operative data on patients as related to the treatment groups

	BPP group (n = 144)	AVP group (n = 144)	P
Indication of revascularization <sup>a</sup>			
Claudication	45 (31)	75 (52)	<.001
Rest pain (Fontaine III)	29 (21)	22 (15)	.280
Ulcer/gangrene (Fontaine IV)	36 (25)	38 (26)	.787
Acute ischemia	25 (17)	7 (5)	.001
Bleeding	8 (6)	2 (1)	.316
Infection	1 (1)	0	.053
Type of revascularization <sup>a</sup>			
Femoral EA + patch	31 (22)	59 (41)	<.001
Femoral EA + patch + PTA <sup>b</sup>	70 (49)	71 (49)	.906
Femoral EA + patch + infrainguinal bypass	30 (21)	6 (4)	<.001
Femoral EA + patch + infrainguinal bypass + PTA	3 (2)	7 (5)	.198
Femoral EA + patch + thrombectomy	10 (7)	1 (1%)	<.001
Other operative characteristics			
Inguinal re-do surgery <sup>a</sup>	34 (24)	7 (5)	<.001
Urgent operation <sup>a</sup>	60 (42)	30 (21)	<.001
Operation time, minutes	242 (55-673)	222, (60-649)	.115

AVP, Autologous vein patch; BPP, bovine pericardial patch; EA, endarterectomy; PTA, percutaneous transluminal angioplasty.  
Data are presented as number (%) or mean (range).  
<sup>a</sup>Variable included in the regression model for estimation of the propensity score.  
<sup>b</sup>Inflow/outflow endovascular treatment.

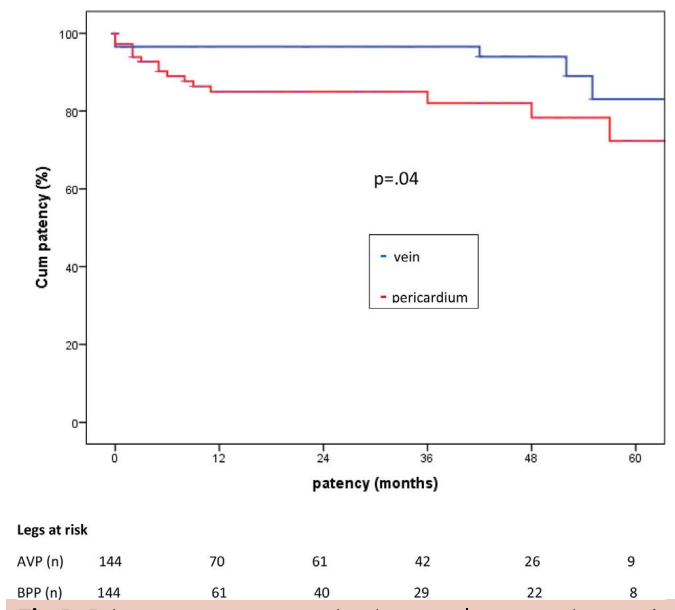
patient of the AVP and BPP groups.  $P < .05$  was set for statistical significance.

## RESULTS

In HUH, 723 femoral endarterectomies were performed from 2014 to 2017. In 144 of these, BPP was used as patch material, and the AVP group included 144 procedures. There were more males in the AVP group (70.8% vs

50.0%;  $P < .001$ ); otherwise, there were no significant differences in the basic demographics (Table I). As for the indications for procedures, claudication was more common in the AVP group (52.1% vs 31.3%;  $P < .001$ ), and acute ischemia was more common in the BPP group (17.4% vs 4.9%;  $P < .001$ ) (Table II).

The patch material in the AVP group was proximal GSV in 53 (36.8%), distal GSV in 58 (40.3%), and anterior accessory vein in 24 (16.7%) procedures. In the BPP group,



**Fig 1.** Primary patency rate in the autologous vein patch (AVP) group and bovine pericardial patch (BPP) group.

Xenosure was used in 77 procedures (53.5%) and Periguard Supple in 67 procedures (46.5%).

The majority of operations in both groups were hybrid procedures (50.7% in the BPP group and 54.2% in the AVP group), whereas femoral endarterectomy alone was more common in the AVP group (41.0% vs 21.5%;  $P < .001$ ). In the BPP group, there were significantly more urgent (41.7% vs 20.8%;  $P < .001$ ) and redo operations (23.6% vs 4.9%;  $P < .001$ ) (Table II).

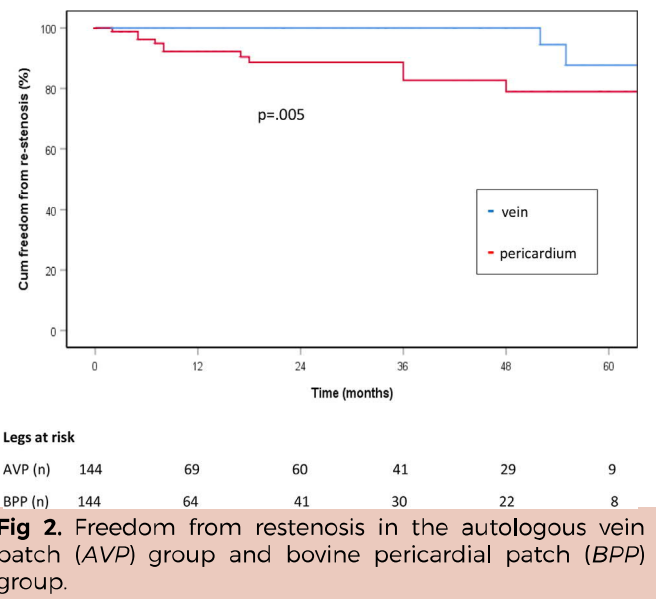
One-to-one propensity score matching provided 92 pairs who underwent femoral patch angioplasty with either vein or pericardium. In the propensity score-matched group, there were no differences in the demographics (Table I) or in the operative data (Table II).

Postoperatively, the patency was verified with imaging or perioperatively for 92 AVP patients (63.9%) and for 121 BPP patients (84.0%) ( $P < .001$ ). The mean follow-up was 19 months (range, 0-78 months).

In the overall series, primary patency at 1 year was  $96.5\% \pm 1.5\%$  for AVP and  $85.0\% \pm 3.8\%$  for BPP,  $96.5\% \pm 1.5\%$  and  $82.0\% \pm 4.7\%$  at 3 years and  $83.0\% \pm 7.7\%$  and  $72.3\% \pm 7.9\%$  at 5 years, respectively ( $P = .04$ ) (Fig 1).

Freedom from restenosis was also superior in the AVP group compared with the BPP group (at 6 months, 100% vs  $96\% \pm 2.2\%$ ; at 1 year, 100% vs  $92\% \pm 3.1\%$ ; at 3 years, 100% vs  $89\% \pm 3.9\%$ ; at 5 years,  $88\% \pm 8.3\%$  vs  $79\% \pm 6.3\%$ ;  $P = .005$ ) (Fig 2).

Reoperation was not a risk factor for restenosis ( $P = .390$ ). Both in univariate and multivariate analysis, urgent operation was associated with increased risk for restenosis (odds ratio [OR] 4.3; 95% confidence interval [CI], 1.4-13.4;  $P = .011$ ).



**Fig 2.** Freedom from restenosis in the autologous vein patch (AVP) group and bovine pericardial patch (BPP) group.

After BPP closure, 12 patients (8.3%) suffered from deep wound infection compared with six patients (4.2%) in the AVP group ( $P = .144$ ). Four bovine patches were removed from the deeply infected surgical wound and were replaced by vein.

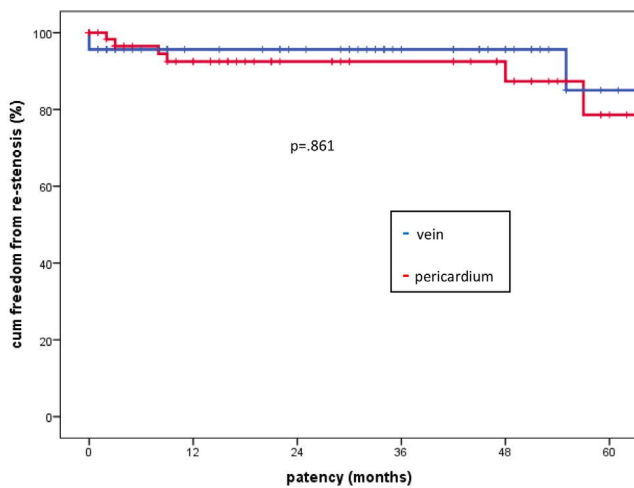
There were no patch ruptures in the BPP group, but there were five (3.5%) in the AVP group ( $P = .024$ ). The ruptures happened shortly after the primary operation (range, 1-8 days). None of the ruptured patches occurred in infected wounds. Four of the patients were reoperated, and they recovered, but one patient was found deceased after patch rupture.

In the 92 propensity score-matched pairs, there was no significant difference in primary patency:  $95.7\% \pm 2.1\%$ ,  $95.7\% \pm 2.1\%$ , and  $85.0\% \pm 9.7\%$  for the AVP group compared with  $92.5\% \pm 3.6\%$ ,  $92.5\% \pm 3.6\%$ , and  $78.6\% \pm 9.9\%$  for the BPP group at 1, 3, and 5 years ( $P = .861$ ) (Fig 3). The freedom from restenosis was 100%, 100%, and  $90.0\% \pm 9.5\%$  vs  $94.3\% \pm 3.2\%$ ,  $89.1\% \pm 4.7\%$ , and  $84.0\% \pm 6.5\%$  at 1, 3, and 5 years for the groups, respectively ( $P = .057$ ) (Fig 4).

**DISCUSSION**

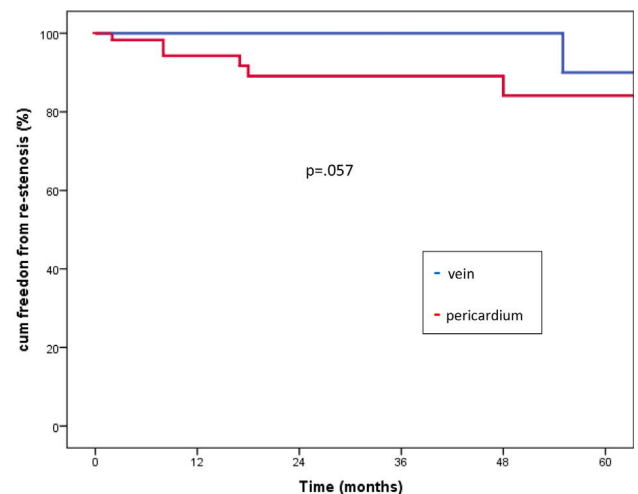
To our knowledge, this is the first study comparing patency of bovine and vein patches in the treatment of atherosclerotic lesions in common femoral artery. Our commendable results on primary patency and freedom from restenosis are in line with other studies<sup>1-3</sup> and confirm open surgery as an effective and durable treatment of atherosclerotic lesions in the common femoral artery.

The exact mechanism behind restenosis after endarterectomy is unclear. It may be due to progression of the atherosclerotic disease. It can also be a consequence of the endarterectomy procedure or related to the patch in the form of intimal hyperplasia. Multiple mechanisms



Legs at risk		0	12	24	36	48	60
AVP	n=92	41	36	23	16	4	
BPP	n=92	44	28	23	18	7	

**Fig 3.** Primary patency rate in 92 propensity score-matched pairs. AVP, Autologous vein patch; BPP, bovine pericardial patch.



Legs at risk		0	12	24	36	48	60
AVP (n)	92	42	37	25	17	5	
BPP (n)	92	45	28	23	18	8	

**Fig 4.** Restenosis rate in 92 propensity score-matched pairs. AVP, Autologous vein patch; BPP, bovine pericardial patch.

are likely to be involved. With BPP, the correct use is imperative: soaking in saline and placing the smooth surface of the patch towards the artery lumen is essential. Some speculations have been presented that if placed accidentally “upside down,” this creates excessive neointimal hyperplasia. Unfortunately, verifying this in our study is not retrospectively possible.

In the overall series, the restenosis rate was significantly higher in the BPP group even though the patency was commendable in both groups (Fig 1). The proportion of urgent operations was significantly higher in the overall series in BPP patients (41.7% vs 20.8%;  $P < .001$ ), and urgent operation was independently associated with increased risk for restenosis (OR, 4.3; 95% CI, 1.4-13.4;  $P = .011$ ). In addition to patency, urgent operations have been associated with overall worse outcome after leg revascularization.<sup>22,23</sup>

The advantage of a registry-based study is avoiding selection bias by including all the patients in the analysis. However, this makes the study population heterogeneous, and the treatment groups may differ markedly with respect to pretreatment covariates. We used the propensity score analysis to minimize the risk of confounding factors, including clinical and operative characteristics, indication, and type of surgery (Tables I and II). One-to-one propensity score matching resulted in two study groups with similar propensity variables. In the propensity score-matched pairs, there were no significant difference in primary patency or freedom from restenosis between AVP and BPP (Figs 3 and 4). Our study indicates that, in terms of patency, BPP is comparable to SVP in femoral endarterectomy.

Our study shows a tendency towards increased deep infection rate in the BPP group (8.3% vs 4.2%;  $P = .144$ ). However, considering the increased risk for postoperative infection related to urgent operations and redo surgeries,<sup>19,24</sup> no conclusions concerning the elevated infection risk can be drawn. Four BPPs were removed from 12 infected wounds. In the study by McMillan et al,<sup>18</sup> BPPs were used in infected fields, and only one of the 16 BPPs had to be removed. It is quite possible that BPPs possess a bacteria-resistant character, but they are not immune from becoming infected.

No patch ruptures occurred after BPP closure. The five vein patch ruptures (3.5%) can be considered notable because rupture is a potentially mortal complication, as was unfortunately also the outcome for one of these five patients. Vein patch ruptures have been described following carotid endarterectomy<sup>11,25</sup> and also following femoral endarterectomy in a report by Berner et al,<sup>13</sup> with similar incidence for rupture (3.4%). Berner et al suggested also that the use of GSV from the calf increases the risk of rupture and recommended abstaining from using it as patch material. In our study, one ruptured patch was proximal GSV, three were distal GSV, and one was anterior accessory vein, whereas the proportion of distal vs proximal GSV was equal overall. So indeed, possibly smaller veins may have a higher risk of rupture, but the number of patients in our study is not sufficient to substantiate this finding.

In the majority of studies on femoral endarterectomy, claudication is the most common indication,<sup>14,26,27</sup> as was also in our study, with 31.3% in the BPP group and 52.1% in the AVP group. Noteworthy and regrettable is

that also three of the patients who suffered patch ruptures were claudicants, for it is self-evident that operating a non-life-threatening condition should not result in a lethal complication. Therefore, our results suggest that BPP is as durable and the safer choice compared with AVP.

**Limitations.** The retrospective nature possibly deteriorates the results of the study, but on the other hand, the results reflect the reality fairly well. The number of patients is relatively low, and therefore differences in complications, such as patch rupture and deep infections, may not become visible.

## CONCLUSIONS

BPP provides compatible results to AVP in femoral endarterectomy in terms of patency and infection risk and may be the safer choice considering the risk of patch rupture.

## AUTHOR CONTRIBUTIONS

Conception and design: KN, MS, SK, MV

Analysis and interpretation: KN, MS, MV

Data collection: KN, MS, SK

Writing the article: KN

Critical revision of the article: KN, MS, SK, MV

Final approval of the article: KN, MS, SK, MV

Statistical analysis: MS, MV

Obtained funding: Not applicable

Overall responsibility: MV

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