



RESEARCH ARTICLE

PPH and Biological Glue and Phytonadione infusion in patients with Cirrhosis and Anticoagulation therapy with high risk of bleeding during and after Stapled Hemorrhoidopexy

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ABSTRACT

Background: Stapled hemorrhoidopexy is a common treatment for grade 3 hemorrhoids. Patients with conditions that increase the risk of bleeding, as cardiac stents usage with clopidogrel bisulfate and liver cirrhosis, should receive an extra care in surgical procedures due to the high risk of bleeding. For this reason and for patients with third degree hemorrhoids we propose the use of stapled hemorrhoidopexy followed by the use of biological glue and the intravenous administration of Phytonadione. Some studies in the literature demonstrate the risks of periprocedural bleeding and post-surgical procedures, generally lasting > 45 minutes and in chemically or pathologically anticoagulated patients as being at high risk of bleeding and death.

Aim: Assess surgical outcomes in patients with hemorrhoids and high risk of bleeding submitted to stapled hemorrhoidopexy followed by biological glue.

Methods: Between 2005 and 2024 172 patients were analyzed, in a retrospective cohort study.

Results: From 86 patients submitted to stapled hemorrhoidopexy followed by the use of biological glue in the local of stapled line, only one (1.16%) presented bleeding in the surgical postoperative (Group 1). Eighty-six patients submitted to PPH procedure and biological glue use, also received 3 days before surgery and 3 days after surgery one dose of 5 mg of Phytonadione (Vitamin K1) per day (Group 2). In this group, no patients presenting rectal bleeding after surgery with the follow up of 3 months. Patients do not have any other complications and pain in the postoperative period. The median (IQR) operative time was 55 min and the median (IQR) length of hospital stay after surgery was 3 days.

Conclusion: Patients with high risk of bleeding submitted to stapled hemorrhoidopexy followed by the use of biological glue (Group 1) presented very low rates of bleeding in the postoperative period. The adjuvant administration of vitamin K1 (Group2) at a recommended dose is proven to better prevent bleeding.

Keywords: Hemorrhoid. Liver cirrhosis. Stents. Clopidogrel, K Vitamin.

Introduction

Hemorrhoidal disease is a frequent involvement since more than 50% of the population over 50 years old has experienced symptoms^{3,4}. The most usual complications of hemorrhoids are heavy bleeding, chronic unremitting prolapse of mucosal tissue, strangulation, ulceration and thrombosis^{2,5}.

A widely treatment of hemorrhoids is procedure for prolapse hemorrhoids (PPH) or stapled hemorrhoidopexy⁶. One complication of this or other hemorrhoid treatments are postoperative hemorrhage¹.

However, in patients with high risk of bleeding, as cirrhosis and cardiac patients with anticoagulation drugs, surgery can result in a larger hemorrhage complicating even more the patient condition.

Therefore, to minimize hemorrhage in patients with high risk of bleeding submitted to surgery we propose the use of procedure for prolapse hemorrhoids together with biological glue.

The aim of this study was to realize an observational retrospective cohort to assess the complications after stapled hemorrhoidopexy and biological glue.

Methods

STUDY OVERVIEW

Data were analyzed retrospectively between 2005 and 2024, from private practice in São Paulo, Brazil. Written informed consent was obtained from all subjects as this is the usual and mandatory practice provided upon admission for all patients and/or those responsible for the same to sign.

STUDY QUESTION

The study was designed to explore the possibility of the absence of bleeding in the postoperative of PPH with the local use of biological glue (Group 1) and administration of vitamin K1 (Group 2) in patients with high risk of bleeding.

INCLUSION CRITERIA

Were included patients with third degree hemorrhoids associated with liver cirrhosis by hepatitis B or C, all of them classified as Child-Pugh C, therefore

with a severe coagulation disorder, acting like a complete anticoagulated patient. Were also included patients with third degree hemorrhoids associated with coronary stent and Clopidogrel bisulfate usage. All patients using stents and Clopidogrel normality had an INR superior to 3, which represents a high risk of bleeding.

STUDY DESIGN

Data was collected from private practice and was analyzed in a retrospective cohort.

PROCEDURES

These 172 third degree hemorrhoids (Figure 1) patients underwent to the technique described by Longo, followed by the use of biological glue. All surgeries were performed by the same surgeon.

All patients were submitted to clinical and laboratorial examinations before surgery. They underwent general anesthesia and were placed in lithotomy position. The circular anal dilator was inserted and sutured in the perineum. Purse string suture anoscope was then inserted and the purse string suture was performed above the dentate line and the anoscope was removed. Circular stapler (Figure 2) was then positioned and closed for about 60 s before fire. After the procedure surgical specimen was removed (Figure 3), suture line was observed (Figure 4) and biological glue was applied (Figure 5).

After the surgery feeding started on the same day, with high fiber diet and laxative diet, plus 2.5 liters of water. Analgesia was performed with acetaminophen and tramadol and whether the pain remained or increased, decimal solution of morphine sulfate was administered.

Eighty-six patients, named Group 1, were operated with this technique described above and other 86 patients (Group 2) operated by the same technique and 5 mg of Phytonadione (Vitamin k1) was administrated by intravenous infusion, twice a day (each 12 hours) per 3 days before surgery and 3 days after surgery. The intravenous infusion rate should not exceed 1 mg/minute. In the Group 2 no patients present anal rectal bleeding during a

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follow-up of 3 months after surgery. Studies demonstrated that use of vitamin K pre-operatively and post-operatively to patients with coagulation abnormalities lead to attenuate the risk of bleeding occurrences and the necessity of blood transfusion ($p=0.02$) and without any risks for stokes or thrombosis^{16,17,18}.



FIGURE 1 – Third degree hemorrhoid



FIGURE 2 – Insertion of circular stapler



FIGURE 3 – Surgical specimen after PPH

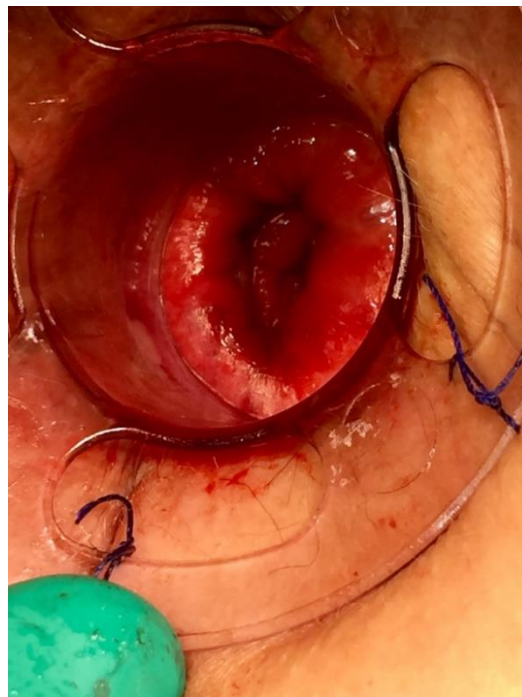


FIGURE 4 – Result after using PPH

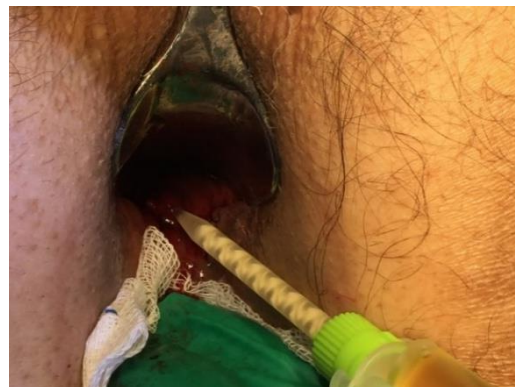


FIGURE 5 – Use of biological glue in the suture line

OUTCOMES

Study primary outcome was the presence or absence of bleeding in the postoperative of PPH and biological glue. Bleeding was assessed by a nurse at each 2 h, until 3th day of postoperative. According to the literature, which is limited, the levels considered as bleeding that should be considered post-operatively in anticoagulated patients or with serious coagulation disorders should be greater than 200 ml/6 hours. Secondary outcomes were presence or absence of pain, which was also assessed by a nurse throughout a pain scale that ranges from 0 to 10 which 0 meaning no pain and 10 meaning the worse pain experienced. Pain and the presence of anal bleeding was assessed every 6 h until day 3 of postoperative. Operation time and length of hospital stay were also assessed.

STATISTICAL ANALYSIS

Categorical variables were analyzed with frequencies. Operation time as procedures lasting > 45 minutes and length of hospital stay were continuous variables and were analyzed with median and interquartile range. Was used Small Stata Software, version 13 (Stata Corp).

Results

PATIENTS' DEMOGRAPHIC INFORMATION

The study included 172 patients with third degree hemorrhoids associated with liver cirrhosis or clopidogrel use. Of the 54 patients with liver cirrhosis 27 were due to hepatitis B and the other

27 to hepatitis C and all of them classified as Child-Pugh C, which represents a poor prognosis and an extremely high risk of bleeding. The other 12 patients were cardiac patients with the use of stents and daily use of Clopidogrel bisulfate as anticoagulant drug. Patients using Clopidogrel bisulfate were with an INR higher than 3, which also represents a high risk of bleeding. Patients with liver cirrhosis and the ones using Clopidogrel bisulfate were predominantly male. In table 1 are represented the baseline characteristics of the 172 subjects submitted to PPH followed by biological glue application and intravenous infusion of vitamin K1.

TABLE 1 – Baseline characteristics

	PPH + Biological glue (n=86) + vit K (n=86)
Gender - n (%)	
Male	152 (88,3%)
Female	20 (11,7%)
Age - years (median - IQR)	64 (23)
Hemorrhoids grade III - no (%)	172 (100%)
Ethiology high risk of bleeding - no (%)	
Cirrhosis class C	54 (31,3%)
Clopidogrel bissulfate	118 (68,7%)

POSTOPERATIVE BLEEDING

Of the 54 patients with hemorrhoids associated with hepatic cirrhosis none had bleeding during postoperative period. Of the 118 patients with hemorrhoid and use of anticoagulant medicaments, only one had bleeding during postoperative (Table 2). In this study, the volume of bleeding considered as a warning in the postoperative period in patients on anticoagulation or with cirrhosis and severe coagulation disorders was greater than 200 ml in 6

hours. This patient presented bleeding of 400 ml during the first 12 h after surgery with no improvement after clinical treatment. This patient was submitted to a new surgery in the 3rd day of postoperative, in which she was sutured with two stitches (Polydioxanone 3-0) in the stapled suture line with bleeding resolution (Table 3). The patient who presented bleeding in the postoperative period belong to Group 1 (without use of vitamin K). Beyond this patient with bleeding there was no other complication reported in our cohort.

TABLE 2 – Percentage of patients with bleeding after surgery

Bleeding	Presence	Absence
Cirrhosis (%)	0.0	100.0
Full Anticoagulation (%)	1.16	98.84

Total (%) 1.16 98.84

TABLE 3 – Bleeding patient information

Blood loss	Gender	Age	Management	Outcome
400 ml	F	78	Reoperation- Two stitches in stapled suture line	bleeding resolution

PAIN AND OPERATION DURATION AND HOSPITAL STAY

All patient reported pain lower than 3 in a scale ranging from 0 to 10 (this scale was defined in the outcomes' section). The median (IQR) time of operation was 55 (12) min and patients stayed in hospital for a median (IQR) period of three 3 (2) days after surgery.

Discussion

Our results suggest that in patients with third degree hemorrhoids and liver cirrhosis or use of stent and Clopidogrel submitted to stapled hemorrhoidopexy followed by the use of biological glue has great results. Of the total cohort only one (1.16%) patient presented bleeding during the postoperative period. This represents a small percentage of the total sample.

Searching in the literature was found two papers similar to our goal. The first one was a study from Anghelacopoulos et al. They did a randomized controlled trial comparing the use of PPH in one group and PPH and biological glue in the other. Their sample included patients with hemorrhoids grade 3 and 4, but without any condition that increase the risk of bleeding. They found results favoring the use of PPH followed by the use of biological glue. The second paper was from Huang et al. They have conducted a study that included patients with hemorrhoids and with liver cirrhosis submitted to PPH; however, they did not use biological glue; 25% of their sample presented bleeding after the procedure.

Despite the samples being a little different, our study shows encouraging results that resemble the results of Anghelacopoulos et al. Their study

showed great results for a broad population while this one present great result for a narrow population. Only with the use of PPH 1.16% of the sample presented bleeding after the procedure as reported by Huang et al. In our study with the use of PPH followed by biological glue 4.5% of our sample presented bleeding in the postoperative. Comparing only patients with cirrhosis our results present 0% of postoperative bleeding against 25% in Huang et al. That suggests that biological glue associated with PPH might decrease postoperative bleeding in cirrhotic patients. According to the literature, which is limited, the levels considered as bleeding that should be considered post-operatively in anticoagulated patients or with serious coagulation disorders should be greater than 200 ml/6 hours^{19,20}. Based on our results, we propose that patients with third degree hemorrhoids with a secondary condition that increases the risk of bleeding should be submitted to stapled hemorrhoidopexy with the use of biological glue to reduce bleeding during the postoperative.

Relevant studies have demonstrated that in patients with chronic full anticoagulation or pre-existing pathological conditions that lead to failure of the coagulation system of these patients, during surgical procedures and up to 2 days afterwards, the risk of bleeding can reach fatality rates of 8% to 10% of cases^{16,17}. Hemorrhoidectomy surgeries have a low bleeding risk classification (2%) for anti-coagulation patients. However, in cases of grade 3 hemorrhoidal diseases with irreducible prolapses or grade 4 and in the presence of bleeding, this risk of bleeding during surgery and even on day 2 of post-operative period can reach rates greater than 4% with serious surgical control difficulties in cases of hemorrhoidectomy^{10,16}.

A very important attention and care are involved during the intravenous infusion of vitamin K1, which never can occur faster than 1mg/minute.

The association of third degree hemorrhoids and liver cirrhosis or stent use is not so frequent. For this reason, the major limitation of our paper is the reduced sample size. To achieve more solid and generalizable results one solution is the conduction of a multicenter prospective study to increase sample size. A prospective study could also help balancing the covariates between groups reducing confounders, that were not assessed in this study. But in surgical areas randomized controlled trial may face challenges as lack of infrastructure, surgeon learning curve and differences in development and research⁷. One factor that may have influenced our results is the great expertise of the surgeon and his team.

Conclusion

Patients with high risk of bleeding submitted to stapled hemorrhoidopexy followed by the use of biological glue and intravenous infusion of vitamin K1 presented very low rates of bleeding in the postoperative period.

Conflict of Interest:

None

Funding Statement:

None.

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