International Journal of Pharmaceutical Science and Research
ISSN: 2455-4685; Impact Factor: RJIF 5.28
Received: 26-05-2020; Accepted: 11-06-2020; Published: 22-06-2020
www.pharmacyjournal.net
Volume 5; Issue 2; 2020; Page No. 08-12

The efficacy of memethol ® spray in patients with hemorrhoids

Abdullah Osman Kocak[1*], Sultan Tuna Akgol Gur[2], Ilker Akbas[3], Zeynep Cakir[4]
[1] MD, Emergency Physician, Assistant Professor, Department of Emergency Medicine, Faculty of Medicine, Ataturk University, Erzurum, Turkey
[2] MD, Emergency Physician, Assistant Professor, Department of Emergency Medicine, Faculty of Medicine, Ataturk University, Erzurum, Turkey
[3] MD, Emergency Physician, Department of Emergency Medicine, Bingol State Hospital, Bingol, Turkey,
[4] MD, Emergency Physician, Professor, Department of Emergency Medicine, Faculty of Medicine, AtaturkUniversity, Erzurum, Turkey

Abstract
Introduction: Hemorrhoids are mucosal cushions around the anus that contain vascular tangles. It is a disease caused by swelling and displacement of these cushions due to various reasons, causing bleeding, pain, itching and discomfort in the person. According to researches, more than 3/4 of people are suffering from hemorrhoids at some point in their lives, and about half of those over age of 50 people need treatment.The aim of our study is to investigate the efficacy of Memethol® Barrier Spray on hemorrhoidal symptoms in patients admitted to the emergency department.
Materials and Methods: Patients admitted to the emergency department with hemorrhoidal symptoms were included in the study. Patients were randomized into two groups by using a simple computer program. One group was designated as a study group and both IV dexketoprofen and Memethol® Barrier Spray are applied on this first group, in another hand the second group was designated as control group and only IV dexketoprofen was applied.The patients were asked to evaluate the pain, itching and discomfort in the rectal area by appraising between 0-10 points with visual analog scale at the beginning, 6th hour and 24th hour.
Results: When the inclusion and exclusion criteria were applied on our study, 44 patients in the study group and 54 patients in the control group complete the study. Although both treatment methods were effective on hemorrhoidal symptoms, statistically Memethol® Barrier Spray was found more effective than IV dextroprofen.
Conclusion: In our study, Memethol® Barrier Spray was found more effective than Dexketoprofen in pain reduction, itching and rectal discomfort in patients admitted to the emergency department with hemorrhoidal symptoms.

Keywords: hemorrhoids; memethol ® barrier spray; emergency medicine

1. Introduction

Arterioles, venules, arteriovenous anastomoses, smooth muscle structures and fibrovascular structures located in the submucosa layer of the anal canal are called “vascular cushions”.These vascular cushions are also available to everyone as an anatomical structure [1]. Hemorrhoids is a diseasecaused by symptomatic enlargement and displacement of these normal anal cushions in the anal canal [2]. Hemorrhoidal cushions are located in 3 different places as the left side, right anterior and right posterior quadrants of the anal canal.In practice, this is expressed in terms of clockwise 3, 7, 11 [3].

The hemorrhoidal artery branches in the cushions produce venous plexus and numerous arteriovenous anastomoses. These cushions swell during defecation and straining to prevent deterioration of the structure of the anal canal epithelium It also provides anal continence and prevents exuding of gas and liquid from the intestines. Anal cushions cling to the mucosa with collagen fibers and muscular fibers.Hemorrhoidal cushions connect to the internal sphincter and longitudinal muscle layer via these fibers. As a result of thinning in collagen fibers, increased intra-abdominal pressure, hard defecation and occasional ruptures, hemorrhoidal cushions slip and prolapse [4].

Although the exact cause of hemorrhoid disease is not known, gravitation, straining and irregular bowel movements are thought to be involved in pathophysiology [3]. The changes in these cushions in the anal canal are as follows; The dilation of the submucosal arteriovenous plexus and thinning of the vessel walls, the contraction of the vascular sphincter with little or no contraction [2].

Hemorrhoids are classified according to location of the hemorrhoidal piles. Internal hemorrhoids are piles that lie above the dental line and are covered with columnar or transitional epithelium.External hemorrhoids remain below the dental line and are covered with squamous epithelium. Internal and external hemorrhoids occur together in mixed type hemorrhoids.

Internal hemorrhoids are divided into 4 groups according to displacement of hemorrhoid piles and patient complaints.

1st Stage of Hemorrhoids: The veins in the anal canal were increased in terms of quantity and wideness, but they do not prolapse towards toexit of the anal canal. Bleeding may be observed during defecation.

2nd Stage of Hemorrhoids: Hemorr hoidal pilesthat prolapse by defecation and/or strainreturn by itself due to decreasing of the pressure. Complaints of the patient increase during this period.

3rd Stage of Hemorrhoids: Hemorrhoidal piles that prolapse towards to exit of the anal canal, can only return back by

pushing with hands. Bleeding and itching are observed.
4thStageof Hemorrhoids: It is the end stage of the hemorrhoidal disease and the hemorrhoidal piles are at the outside of the anal canal constantly independently of the defacation. The complaints such as bleeding, pain and itching are increased [5, 6].
According to researches, more than 3/4 of people are suffering from hemorrhoids at some point in their lives, and about half of those overage of 50 people need treatment.Hemorrhoidal disease is more common in men. Relaxation of the supportive muscles and ligaments in the anal area because of constipation, diarrhea, old age and other reasons, increasing on width on the cushions with increased venous pressure by straining, inadequate pulp of nutrition, obesity, pregnancy, sedentary lifestyle, some sports such as doing crunches and weight lifting, occupations that require sitting or standing continuously, chronic lung or liver diseases, intra-abdominal tumors can lead to hemorrhoid disease [7, 8].
Symptoms in hemorrhoids disease are due to displacement of the hemorrhoidal cushions as a result of vascular congestion secondary to obstruction in the bloodstream and weakening of the tissues supporting the anorectal junction (collagen and elastin).

- Rectal Bleeding:The main symptom of the symptomatic hemorrhoids is the rectal bleeding that cause to consult a doctor. Bleeding may occur during and after defecation. Its color is always bright red that refers recent bleeding.
- Pain: Generally internal hemorrhoids do not cause to pain. However, it may be painful due to thrombus which may develop in advanced stages. External hemorrhoids cause intense pain that starts in the form of an acute attack and lasts for about one week, because of severe somatic innervation occuring at the site of development, especially in the event of thrombus formation. Pain is continuous and may increase during or after defecation.
- Edema and Prolapse: When the internal hemorrhoids are mobilized downward and prolapse from the anal canal, they are felt by the patient and defined as a mass. This condition is felt as fullness and pain and it is defined as the need for defecation and inability to fully relax.
- Itching: Itching is seemed by associated with mucus secretion, especially in patients with prolapse [9, 10]

The aim of our study is to investigate the efficacy of Memethol® Barrier Spray on hemorrhoidal symptoms in patients admitted to the emergency department.

2. Material method

Type of Study

Our study is a prospective study and it was conducted on a voluntary basis and was performed on patients who agreed to participate in the study.

Study Centre and Period

The study was carried out between 01.01.2019-28.02.2019 in Ataturk University, Medical Faculty, Emergency Medical Clinic.

Inclusion Criteria

- Patients diagnosed with hemorrhoidal disease
- Patients with complaints related to hemorrhoidal disease
- Patientsovertheage of 18 yearsold
- Volunteer to participate in the research
- No hearing impairment
- Abletocommunicate in Turkish Language
- Having stable vital signs

Exclusion Criteria

- Not volunteering to participate in the research
- Having any chronic disease (Congestion heart failure, coronary artery disease, COPD, previous stroke, chronic renal failure, chronic liver disease)
- Patients who have not completed the study
- Having any other anorectal disease (abscess, hematoma, pilonidal sinus, cancer)
- Patients who have thrombosed hemorrhoids

The patients were informed about the objectives of the study, the method of application and the gains of the results obtained.

Application of the Study

Patients who applied to the Emergency Clinic with pain due to hemorrhoidal disease were included in the study. During the study, the patients were divided intotwo groups as study group and control group. Patients included in the study were randomized with a simple computer program. Both groups received NSAID (IV 50 mg dexketoprofen, 100 cc isotonic within 5 minutes).Memethol® Barrier Spray was also applied to the study group additionally.4 sprays of Memethol® Barrier Spray were applied to the patients in the emergency service. Than the patients were informed that 4 sprays of Memethol® Barrier Spray should be applied every 8 hours. Age and sex data of the patients were recorded.Patients were also asked to score the pain, itching, and discomfort level in the anal area between 0 and 10 at the time of admission, at the 6th hour after the first spray application and at the 24th hour after the first spray application. The 6th and 24th hour data were obtained by telephone.

Data Analysis

Statistical analyses were performed using SPSS 20 statistical analysis program (IBM). Data are presented as mean, standard deviation, and median; and with the minimum and maximum values, percentages, and numbers. Shapiro-Wilk and Kolmogorov – Smirnov tests were used to evaluate whether the data conformed to a normal distribution. Independent samples t-test was used for comparing normally distributed data between two independent groups, and the Mann–Whitney U test was used if the data were not normally distributed. Categorical variables were compared using Chi-square and Fisher's exact tests. A p value of <0.05 was considered to be statistically significant

3. Results

The study was started with 60 patients in both groups, but the study group was completed with 44 patients and the control group with 53 patients.
Patient flow diagram is summarized in Figure-1. The average age of the patients in our study was 40.06 ± 14.44 (minimum age is 18, maximum age is 85).There was no statistically significant difference between the groups ($p> 0.05$). 70 (72.2%) patients who participated the study were male. There was no gender difference between the patient groups included in the study ($p> 0.05$).The initial pain values of the two groups included in the study were 7.11 in the study group and 7.14 in the control group.In the questioning about itching, the

study group evaluated the uncomfortable feeling of itching as 7.11 and the control group as 7.17. When the feeling of discomfort in the rectal area was questioned, the study group evaluated it as 7.05 and the control group evaluated it as 7.17.It was seen that there was no difference between the patients at the time of admission. This result was also shown statistically ($p > 0.05$).The pain scores at the 6th and 24th hours of the study group were 4.32 and 2.27, respectively, and 6.04 and 4.4 in the control group, respectively, and this was statistically significant ($p < 0.05$). In the evaluation of itching sensation, the values of the study group at the 6th and 24th hours were 5.86 and 3.82, respectively, and the values of the control group were 6.64 and 5.79, respectively. In this case, it was statistically significant. In the evaluation of the feeling of discomfort felt in the rectal area, the 6th and 24th hour values of the study group were 5.20 and 3.11, respectively, while the values of the control group were 6.06 and 4.3, respectively. In this case, it was statistically significant. The results obtained from our study are shown in figure-2.

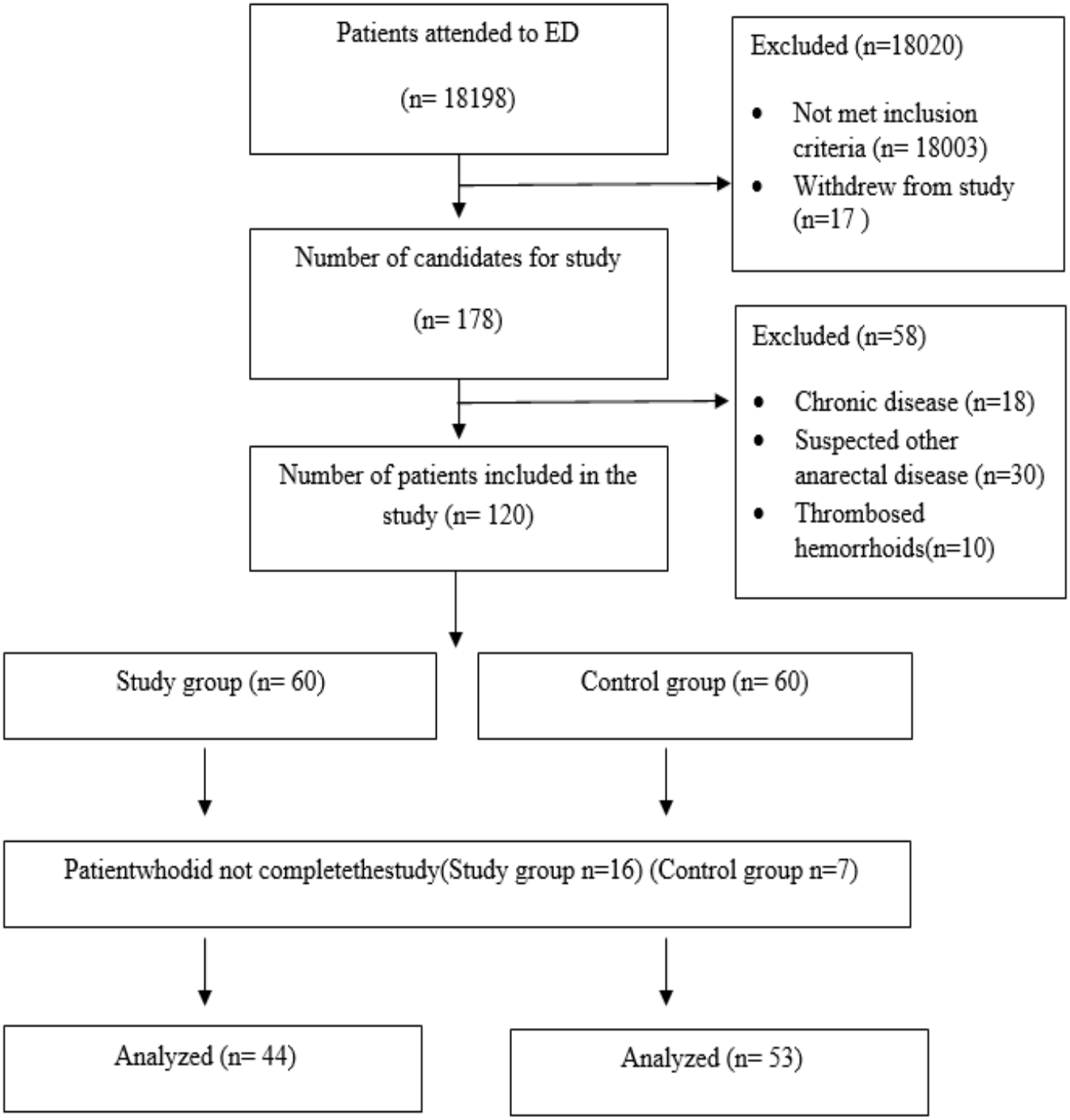

Fig 1: Flow diagram of the study

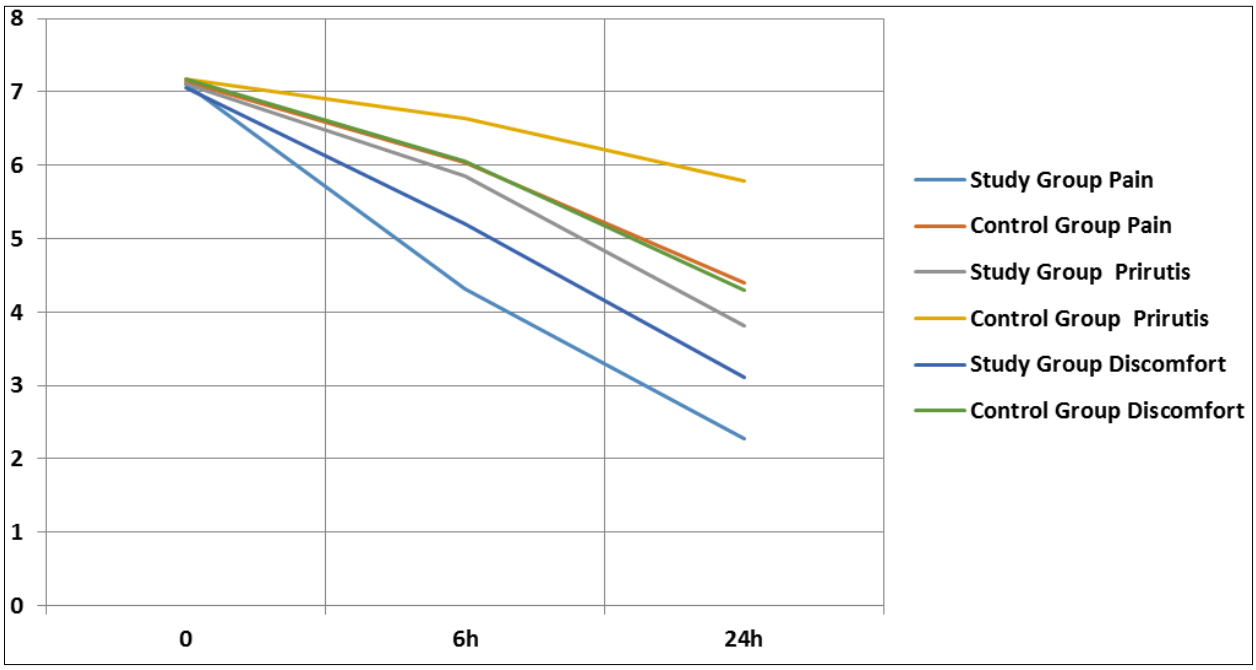

Fig 2: Data obtained from the study

4. Discussion

When the etiopathogenesis of hemorrhoidal disease is examined, three main theories are proposed: mechanical theory, hemodynamic theory and sphincter dysfunction theory. According to the mechanical theory, musculofibro elastic connective tissue loses its function with the disruption of its structure over time and the vessels in the region expand, lengthen and become curved and become varicose.Hemorrhoidal disease occurs as a result of bleeding caused by thinning the surfaces above the mucosa with increasing pressure. In hemodynamic theory, it is thought that the complete flow of blood coming to this area through arteries cannot be achieved.

Venous blood flow decreases due to an increase in abdominal pressure (pregnancy, straining, weight, etc.), thus causing swelling of the hemorrhoid cushions and slowing or stopping of venous blood flow, causing clot formation in the veins and thrombosis of the vessels in the anal area. This thrombosis causes hemorrhoidal symptoms. In the theory of sphincter factors; abnormalities in sphincter pressure seen in patients with hemorrhoidal disease have been reported. When the anal sphincter does not expand sufficiently, the pressure increases, blood lapses in the vein and hemorrhoidal disease occurs [9-11].

There are many approaches in the treatment of hemorrhoidal disease. When the disease is clinically divided into four degrees, the common view is that lifestyle changes, medical treatment and/or non-surgical interventions (rubber band ligation, sclerotherapy etc.) are used in the treatment of first and second stage of hemorrhoids, and surgical treatment methods are used in the third and fourth stage of hemorrhoids [8].

The treatment plan is evaluated under four main headings: 6, 14, 16

- Regulation of lifestyle and nutrition habits
- Medicines
- Mucosa fixing methods
- Surgical treatment

Regulation of lifestyle and nutrition habits: Delaying of defecation, straining for a long time, staying in the toilet for a long time (reading books or newspapers in the toilet), and self-compulsion should not be used to defecate.It is useful to consume plenty of pulp foods, avoid constipation foods, drink plenty of water, keep the anus clean and lose weight.Tight clothing, spicy foods and alcohol should be avoided. A hot sitting bath can reduce pain by lowering the resting pressure of the anus [12-14].

Hygiene of the anal area is one of the most important steps in the struggle against hemorrhoidal symptoms.The risk of microbial infection increases when anal area hygiene is not achieved.After defecation, cleaning with usual water followed by drying should be done by touching, not wiping.Private bathtubs are available for down-to-waist cleaning. Excessive cleaning of the anal area with soap and water can cause major problems. Excessive cleansing removes natural oils from the anal skin and causes flora to deteriorate. Impaired flora also increases the risk of infection and inflammation. Developing infection and inflammation activate hemorrhoidal symptoms [14].

Drugs: Drugs evaluated in this category act with different mechanisms. These drug groups include laxative drugs that provide softening of feces, flavonoids that increase vein tone and calcium dobesylate preparations. The laxatives soften the stool and reduce the pressure in the rectum, thus reducing pain. Drugs acting on the veins increase the venous " tone and decrease the pressure in the vessels, thus reducing the hemorrhoidal symptoms.Drugs in this group also reduce the edema in the anal region by regulating the permability of capillaries [7, 15]. Micronized purified flavonoid fraction (MSFF) is used astablets containing 90% diosmin (450 mg) and 10% hesperidine (50 mg) [16]. Calcium dobesylate; is a preparation presented in capsule form and has similar mechanisms of action as MSFF. Its biochemical content is calcium 2,5-dihydroxybenzenesulfonate [10].

Other drug groups used in this group are analgesic drugs. Analgesic drugs are effective in reducing pain by acting

systemically. Local anesthetics are locally applied drugs and are used in the treatment of pain accompanied by local itching.There is not enough evidence of this effect of local anesthetics. Lidocaine ointments are most commonly used as local anesthetics [7, 9, 10, 17].

Mucosa fixation methods: Band ligation, Infrared photocoagulation, Cryotherapy methods are included in these methods.Many complications such as urinary retention, bleeding, perianal abscess, pain, infection can be seen because of that they are interventional operations [7].

Surgical operations: Surgical intervention can be performed in advanced stage hemorrhoids that do not respond to medications and other precautions and are accompanied by additional conditions such as fissure and fistula [7].

Memethol® Barrier Spraycontains (1R, 2S, 5R) -2-isopropyl-5-methylcyclohexanol, sodium hydrogen carbonate, 7- (dimethylamino) phenothiazin-3-ylidene] -dimethylazanium; chloride, 1, 2-propanediol, deionized water. Memethol® Barrier Spray relieves pain and itching the most important symptoms of hemorrhoids by a non-pharmacologicalmeans.Memethol® Barrier Spray is not a drug.Memethol® Barrier Spray forms a mechanical barrier in the outermost layer of the skin, protecting the irritated anal area against microbial agents. Film formation allows the product to remain in the epidermis. The product pH is compatible with the anal region. The pain, piles, itching, swelling and hygiene problems are resolved, anal injuries (fissure) and hemorrhoids patient return to everyday life quality is achieved by use Memethol® Barrier Spray.During treatment it is expected that hemorrhoid piles shrink and reduce to invisible dimensions day to day [18].

In our study, it was found that there was a significant decrease in pain, itching and discomfort in the anal area in patients who admitted to the emergency service because of suffering from hemorrhoidal symptoms. Since the main reason of admission to the emergency service of patients with hemorrhoids was pain, application of NSAID (dexketoprofen) was preferred for the control group in our study. According to our study, Memethol® Barrier Spray is a more effective treatment methodthan dexketoprofenin emergency service.The primary aim of the treatment of hemorrhoid disease is to provide symptomatic relief, regression of the stage in advanced stage hemorrhoidal disease and to eliminate the necessity of surgical treatment(9, 10).The quantity of patients with symptoms of hemorrhoidal disease are quite high. Only a few of the patients who have anorectal complaints consult to the doctor because of the reasons as fear of cancer, fear of pain, religious feelings, and anxiety of embarrassment. Many of these patients often treat themselves with local treatment [12, 19]. It is approved viaour study that Memethol® Barrier Spray which is used locally in the reduction and eliminating of hemorrhoidal symptoms, is an effective treatment method.

5. Conclusion

In our study, Memethol® Barrier Spray was found to be more effective than Dexketoprofen in pain reduction, itching and rectal discomfort in patients who admitted to the emergency service with hemorrhoidal symptoms. Further research is suggested on this subject.

6. References

1. Burch J, Epstein D, Baba-Akbari A, Weatherly H, Fox D, Golder S, *et al.* Stapled haemorrhoidectomy (haemorrhoidopexy) for the treatment of haemorrhoids: a systematic review and economic evaluation. Health Technol Assess. 2008; 12(8):1-193.
2. Yetkin E, Ileri M. Dilating venous disease: Pathophysiology and a systematic aspect to different vascular territories. Med Hypotheses. 2016; 91:73-6.
3. Johanson JF. Nonsurgical treatment of hemorrhoids. J Gastrointest Surg. 2002; 6(3):290-4.
4. Lohsiriwat V. Approach to hemorrhoids. Current gastroenterology reports. 2013; 15(7):332.
5. Pares D, Abcarian H. Management of Common Benign Anorectal Disease: What All Physicians Need to Know. Am J Med. 2018; 131(7):745-51.
6. Lohsiriwat V. Anorectal emergencies. World J Gastroenterol. 2016; 22(26):5867-78.
7. Ekçi B, İzbırak G, Gökçe Ö, Tanrıöver Ö. A practical approach to haemorrhoidal diseases in primary care. Turkish Journal of Family Practice. 2009; 13(2):87-92.
8. Kann BR, Whitlow CB. Hemorrhoids: diagnosis and management. Techniques in Gastrointestinal Endoscopy. 2004; 6:6-11.
9. Ray-Offor E, Amadi S. Hemorrhoidal disease: Predilection sites, pattern of presentation, and treatment. Ann Afr Med. 2019; 18(1):12-6.
10. Sun Z, Migaly J. Review of Hemorrhoid Disease: Presentation and Management. Clin Colon Rectal Surg. 2016; 29(1):22-9.
11. Gecim I. Hemorrhoidal Disease. Journal of Turkish Association of Colorectal Surgeons. 2011; 21(4):145-59.
12. Ersan Y, Yavuz N, Ergüney S, Kuflaslan R. Hemoroidlerin medikal tedavisi. Cerrahpasa Tıp Dergisi. 2003; 35(4):188-93.
13. Pigot F, Siproudhis L, Allaert FA. Risk factors associated with hemorrhoidal symptoms in specialized consultation. Gastroenterol Clin Biol. 2005; 29(12):1270-4.
14. Sardinha TC, Corman ML. Hemorrhoids. Surg Clin North Am. 2002; 82(6):1153-67.
15. Akin ML, Colak T, Erenoglu C, Celenk T, Batkin A. The efficacy of oral flavonoid, band ligation and sclerotherapy in the treatment of hemorrhoidal disease. Journal of Contemporary Surgery. 2000; 14:96-101.
16. Ho YH, Tan M, Seow-Choen F. Micronized purified flavonidic fraction compared favorably with rubber band ligation and fiber alone in the management of bleeding hemorrhoids: randomized controlled trial. Dis Colon Rectum. 2000; 43(1):66-9.
17. Kayaalp O. Local preparations against anal and rectal disorders. Turkey Drug Guide. 2007; 1:59-60.
18. Gumusel B. Clinical Overview Memethol Barrier Spray. Hacettepe University Faculty of Pharmacy; 2013.
19. Jonas M, Scholefield JH. Anal Fissure. Gastroenterol Clin North Am. 2001; 30(1):167-81.