

**AN INVESTIGATION INTO THE RELATIONSHIP BETWEEN HEMORRHOID
DISEASE AND THE USE OF SMARTPHONES IN THE LAVATORY**

Unique Protocol ID: 12/22/2017 – 051

Date: February 11, 2018

Tarih :
Versiyon :

STUDY PROTOCOL

The objective of medical research: A changing world not only brings about different lifestyles and diverse eating habits, it also changes the causes and courses of known diseases. The goal of this study is to examine the relationship between hemorrhoids, a common complaint, and the use of smartphones, also a common feature of modern life, in the lavatory.

The scientific basis and validity of medical research: As is known, hemorrhoidal disease is a frequently observed disease of the lower rectum and anal region that seriously impairs the patient's quality of life. Its worldwide prevalence is reported to be approximately 4.4% [1, 2]. One out of every two people over the age of 50 is reported to experience symptomatic hemorrhoidal disease, with increased frequency with age, especially after the age of 45 [3].

The underlying physiopathological event is vascular enlargement of the lower rectum [2]. Hemorrhoids are classified as internal or external, and it is assumed that the same pathological mechanisms operate in both types (**Figure 1**). Accepted pathological mechanisms and predisposing factors are summarized as follows:

Reduced venous drainage

Many researchers believe that foods low in fiber reduce stool caliber and cause an increase in straining during defecation, thereby increasing the pressure on the anal region [4]. The increased pressure in the anal region leads to prolapsed hemorrhoids and at the same time inhibits venous return. The inhibition of venous return further increases the prolapse of hemorrhoids thus rendering it symptomatic. Hemorrhoids may also develop via the aforementioned mechanism in situations where pressure is augmented such as pregnancy and increased anal sphincter tone. Sitting on the toilet for a long time (for example, while reading a newspaper) has been determined to inhibit venous drainage (the tourniquet effect) [5]. Together with aging, the weakening-loosening of the connective tissue supporting hemorrhoid papillae accelerates the development of hemorrhoidal disease.

Straining and constipation

Chronic constipation and straining have long been recognized as the primary cause of hemorrhoidal disease. Although there has been a number of studies that support this, data that do not support this conclusion have also been reported [4-6]. It is generally accepted that

Tarih :

Versiyon :

increased pressure in the anal canal is greater in those with hemorrhoidal disease and that this pressure decreases following surgery.

Pregnancy

The effect of pregnancy on the development of hemorrhoids is evidenced by the postpartum disappearance of hemorrhoidal symptoms. Increased intra-abdominal pressure and hormonal changes experienced during pregnancy may cause hemorrhoids [7-9].

Portal hypertension and anorectal varices

Although anorectal varices are often accompanied by portal hypertension, symptomatic hemorrhoids are not often observed in patients with portal hypertension [10, 11]. In cases of bleeding the varices should be sutured. Hemorrhoidal disease also regresses with the resolution of underlying liver problems.

Other risk factors

Other factors believed to be related to the development of hemorrhoids include the following: Higher socio-economic status, chronic diarrhea, family history, obesity, anal intercourse, hepatic diseases, inflammatory bowel diseases, rectal surgery, colon cancer, and spinal surgery.

Given the pathophysiological and accelerating factors described above, an increase in hemorrhoidal disease in modern society is to be expected. People today prefer a more sedentary lifestyle and partake of a low-fiber diet richer in high calorie/high fat foods compared with previous generations. In addition, smartphones have invaded nearly every aspect of daily life. In clinical observations, the investigators have found that the use of mobile phones in the lavatory has become a habit for some people. This habit, which increases the time spent on the toilet, is also thought to lead to an increase in pressure on the anal region and straining during defecation. The investigators have not encountered any studies in the literature investigating the relationship between these two situations (smartphone use in the lavatory and the development of hemorrhoids). There is therefore a gap in the literature examining this relationship. Researching this relationship by means of the scientific method should reveal important information. The basic research question of the present study is thus designed to determine to what extent the use of smartphones increases time spent in the lavatory and whether there is an association between this increase in time and hemorrhoidal disease.

Tarih :

Versiyon :

Study protocol, methods, and procedures:

This clinical study will be conducted with a cross-sectional design based on retrospective observation (Figure 2). Apart from the target population there will be a control group. In retrospective studies the selection of the control group is of the utmost importance. Other than the risk factor that is being investigated (the use of smartphones), factors that affect the development of hemorrhoidal disease are similar for the study group and the control group, thus minimizing confounding factors. The control group, as will be noted, will thus have a social environment resembling that of the study group. It should also be noted that members of the control group will be completely healthy, with no health problems (e.g., hearing or visual disturbances) that could affect their use of the risk factor (smartphones).

The study population consists of patients with complaints of hemorrhoids referred to the General Surgery Polyclinic. The control group is comprised of healthy volunteers with no complaints of hemorrhoids (Figure 3). Both the study group and the control group will include persons of both genders between 16 and 65 years of age. Informed consent will be obtained from patients and volunteers, following which a Likert-type survey will be given to each participant to complete (Table 1, questionnaire form). A pilot study will be conducted for the factor analysis of the questions to be asked in the questionnaire. In the pilot study, the target will be to survey 100 patients. After the factor analysis is performed on 100 patients, the questionnaire that is developed will be used in the main study.

As no prevalence study was previously performed for the sample size, it will be calculated based on the prevalence (frequency of smartphone use in the lavatory in the study group and the control group) determined after the pilot study, accepting a type I error of 0.005 and a type II error of 0.20 (80% test power).

The doctor who performs the examinations will be blinded to the questionnaire results. After completion of the questionnaire, the patient's anal region and rectum will be examined by a general surgeon and the presence or absence of hemorrhoids will be noted. Subsequently, if hemorrhoids are present, they will be recorded as either external or internal. Internal hemorrhoids will then be staged as first-degree, second-degree, third-degree, or fourth-degree, according to standard textbook definitions [2].

Primary endpoints of the study:

1) determination of the stage of hemorrhoids in patients with complaints of hemorrhoids

Tarih :

Versiyon :

2) frequency and duration of smartphone use in the lavatory for those with smartphones

Statistical Data Analysis:

All data will be analyzed using the SPSS version 20 package program. The data will consist of categorical nominal and continuous numerical variables. Frequency and percentages will be given for categorical and nominal variables. Following testing for normal distribution of numerical variables, those with normal distribution will be expressed as mean \pm standard deviation, while variables without normal distribution will be expressed as median value and minimum - maximum. The relationship between the risk factor and the outcome variable will be assessed using the Chi-square test. The difference between hemorrhoid stages in terms of exposure times to the risk factor will be determined by ANOVA or the Kruskal-Wallis test. A *p* value of 0.05 will be accepted as statistically significant.

Tarih :

Versiyon :

REFERENCES

1. Haas PA, Haas GP, Schmaltz S, Fox TA Jr. The prevalence of hemorrhoids. *Dis Colon Rectum*. 1983; 26: 435-439.
2. Lowney JK, Fleshman JW Jr. Benign disorders of the anorectum (pelvic floor, fissures, hemorrhoids, and fistulas). In: Zinner MJ, Ashley SW, eds. *Maingot's Abdominal Operations*. 11th ed. New York: McGraw-Hill; 2007: 663-693.
3. Fox A, Tietze PH, Ramakrishnan K. Anorectal conditions: hemorrhoids. *FP Essent* 2014; 419: 11-19.
4. Gibbons CP, Bannister JJ, Read NW. Role of constipation and anal hypertonia in the pathogenesis of haemorrhoids. *Br J Surg*. 1988; 75: 656-660.
5. Johanson JF, Sonnenberg A. The prevalence of hemorrhoids and chronic constipation. An epidemiologic study. *Gastroenterology*. 1990; 98: 380-386.
6. Johanson JF, Sonnenberg A. Constipation is not a risk factor for hemorrhoids: a case-control study of potential etiological agents. *Am J Gastroenterol*. 1994; 89: 1981-1986.
7. Wald A. Constipation, diarrhea, and symptomatic hemorrhoids during pregnancy. *Gastroenterol Clin North Am*. 2003; 32: 309-322, vii.
8. Staroselsky A, Nava-Ocampo AA, Vohra S, Koren G. Hemorrhoids in pregnancy. *Can Fam Physician*. 2008; 54: 189-190.
9. Gojnic M, Dugalic V, Papic M et al. The significance of detailed examination of hemorrhoids during pregnancy. *Clin Exp Obstet Gynecol*. 2005; 32: 183-184.
10. Bernstein WC. What Are Hemorrhoids and What Is Their Relationship to the Portal Venous System. *Diseases of the Colon & Rectum*. 1983; 26: 829-834.
11. Misra SP, Dwivedi M, Misra V. Prevalence and factors influencing hemorrhoids, anorectal varices, and colopathy in patients with portal hypertension. *Endoscopy*. 1996; 28: 340-345.

Tarih :

Versiyon :