

Normative values of the balloon expulsion test in healthy adults

Balon atma testinin sağlıklı erişkinlerde normatif değerleri

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Background/aims: Constipation is the most frequent complaint of the digestive tract. It has been reported that approximately half of the patients with constipation have functional defecation disorders (dysynergic defecation). An important diagnostic tool for the diagnosis of functional defecation disorders is the balloon expulsion test. Normative values have not been widely determined in different populations. We aimed to determine the data which could be indicative of normative values of the balloon expulsion test for healthy individuals in our society.

Methods: A total of 116 healthy volunteers were evaluated in the study (55 men). Subjects were classified into three subgroups according to age (20-39 yrs, 40-59 yrs, ≥60 yrs). Catheters with balloon and application room were standardized, and then a balloon expulsion test was performed in all groups. The results of the balloon expulsion test were statistically compared between groups. **Results:** The distribution of males/females according to age groups was: 20-39 yrs: 20/22, 40-59 yrs: 20/23, ≥60 yrs: 15/16. The balloon expulsion time was determined as 44.1±19.0 seconds in male subjects and 56.4±21.4 seconds in females (p=0.001). An increase in the balloon expulsion time was observed to be related with age in males (p=0.0001); however, no statistically significant difference was shown by age in female subjects (p=0.80). If the entire study group was considered, there was a significant correlation between age and balloon expulsion time (p=0.0001). **Conclusions:** The balloon expulsion test is a simple procedure to identify impaired evacuation in constipated patients. This study represents the first assessment of the balloon expulsion test in a healthy Turkish population. It has been demonstrated that expulsion should take less than 30 seconds for men younger than 40 years of age and less than 1 minute above 40 years. For women, expulsion should occur in 1 minute regardless of age. Our results could serve as a valuable resource of normative data.

Key words: Balloon expulsion test, normative values, healthy subjects

Amaç: Konstipasyon en sık görülen sindirim sistemi şikayeti-dir. Konstipasyonu olan hastaların yaklaşık yarısında fonksiyonel defekasyon bozukluğu (dissinerjik defekasyon) olduğu bildirilmiştir. Fonksiyonel defekasyon bozukluğu tanısında kullanılan fizyolojik kriterlerden birisi de balon atma testidir. Toplumumuzdaki sağlıklı bireylerde balon atma testi için normaleri gösterebilecek bir veri henüz bulunmamaktadır. Bu çalışma ile Türk toplumunda balon atma testi için normal kabul edilebilecek değerlerin belirlenmesi amaçlanmıştır. **Yöntem:** Çalışmaya 55 erkek ve 61 kadından oluşan toplam 116 sağlıklı gönüllü birey alındı. Araştırma grubu yaş dağılımına göre üç gruba ayrıldı (20-39 yaş, 40-59 yaş ve ≥60 yaş). Uygulamalar sırasında kullanılan balonlu kateterlerin ve işlemin yapılacağı ortamın standardizasyonu sağlanarak araştırma grubuna balon atma testi uygulandı. Gruplar arasında balon atma testi süreleri istatistiksel olarak karşılaştırıldı. **Bulgular:** Yaş gruplarına göre erkek/kadın dağılımı 20-39 yaş arası: 20/22, 40-59 yaş arası: 20/23, ≥60 yaş: 15/16'dır. Erkeklerde balon atma zamanı ortalama 44.1±19.0 saniye saptanırken, kadınlarda 56.4±21.4 saniye saptandı (p=0.001). Erkeklerde yaş ile beraber balon atma zamanında artış olduğu gözlenirken (p=0.0001), kadınlarda istatistiksel fark izlenmedi (p=0.80). Tüm çalışma grubu değerlendirildiğinde ise yaş ile balon atma zamanı arasında anlamlı korelasyon saptanmıştır (p=0.0001). **Sonuç:** Konstipasyonlu hastalarda bozulmuş evakuasyonu değerlendirmede basit ve yararlı bir test olan balon atma testinin normalleri ortaya koyulmuş olup normal değerlerin erkeklerde 40 yaş altında 30 saniyeden kısa ve 40 yaş üzeri grupta ise 1 dakikadan kısa olduğu gösterilmiştir. Kadınlarda ise tüm yaş gruplarında normal değer 1 dakika olarak belirlenmiştir. Bu çalışma Türkiye'de sağlıklı bir popülasyonda balon atma testinin değerlendirildiği ilk çalışmadır.

Anahtar kelimeler: Balon atma testi, normal değerler, sağlıklı bireyler

INTRODUCTION

Constipation is merely a symptom -not a disease- and can be defined by subjective or measurable definitions such as excessive straining or incomplete evacuation, less than three bowel movements per week, and prolonged whole-gut or colonic transit. Approximately 63 million people in North America meet the Rome II criteria for constipation (1), which is a common digestive complaint especially for women of all ages. Constipation increases with age, but the stool frequency is unchanged (2). The constipation prevalence was reported as 5.4-11.9% in the Turkish population in a country-wide study (Bor et al. unpublished data).

There are two main syndromes of constipation aside from the secondary conditions - slow colonic transit and evacuation difficulties (functional defecation disorders). Slow transit constipation refers to a clinical syndrome attributable to ineffective colonic propulsion and is thought to have as a primary defect slower than normal movement of contents from the proximal to the distal colon and rectum. In some individuals, the basis for slow transit may be dietary or even cultural. In others, slow colonic transit probably has a true pathophysiologic basis, although little is known about these mechanisms (3).

Functional defecation disorders are defined as paradoxical contraction or failure to relax the pelvic floor muscles during attempted defecation (dyssynergic defecation) or inadequate propulsive forces during attempted defecation (inadequate defecatory propulsion) (4). In many patients, there is an overlap because colon transit is delayed in two thirds of patients with difficult or disordered defecation (5). Identification of functional defecation disorders is essential because of the therapeutic implications in clinical practice (such as biofeedback therapy).

Balloon expulsion is a valuable test in which patients are asked to expel balloons filled with water or air from the rectum. Rao (6) has recommended that the inability to expel a balloon or stool-like device such as a fecom within 3 minutes is one of the physiologic criteria to diagnose dyssynergic defecation. Recently, it has been defined as one of the diagnostic criteria for the definition of functional defecation disorders by the Rome III group (4). This test has high specificity and negative predictive value for identifying constipated patients without dyssynergic defecation (7). Therefore, this

simple test could be useful to determine which constipated patients require more specific studies. However, among the studies that have used the balloon expulsion test for diagnosis of functional constipation, the methodology for balloon expulsion is not uniform. Furthermore, the normal range of balloon expulsion time has not been widely studied in healthy adults. In this study, we investigated the balloon expulsion test in order to define its normative values in our healthy population.

MATERIALS AND METHODS

Subjects

A total of 116 healthy volunteers were recruited from the relatives of patients who admitted to the Hepatology and Reflux Outpatient Clinics of Ege University School of Medicine. Age and gender-matched subjects were recruited within groups according to age stratification (20-39 yrs, 40-59 yrs, ≥ 60 yrs). Written informed consents were obtained from all subjects and the study protocol was approved by the Ege University Human Ethics Committee (05-12/16). Only subjects who reported normal bowel function, were older than 20 years and were of adequate mental status to collaborate in this functional test were selected. All subjects were evaluated with a detailed history. They were not taking any medication that could interfere with bowel function and had no history of previous surgery. All of these subjects had a normal physical examination.

Balloon Expulsion Test

For the balloon expulsion test, a standard fusiform-shaped latex balloon (size 4x9 cm) was used (MMS, Netherlands). These balloons were tied to the tip of the flexible catheters (diameter: 3 mm), and other tip of the catheters was closed with a three-way stopcock. The balloon expulsion test was performed in all subjects. After the procedure had been explained to the participants, the catheter with balloon was placed into the rectum and the balloon was then filled with 60 ml of air from a syringe via the three-way stopcock. The subjects were asked to sit on a commode and expel the balloon, in privacy. A team member recorded the time taken for expelling the balloon.

Statistical Analysis

Analyses were done by Statistical Package Program (SPSS 15.0 for Windows). Comparison of normally distributed numeric data between two gro-

ups was performed with Student's t test and for nonparametric distributed numeric data between three or more groups with Kruskal-Wallis test. Statistical significance level was assigned as $p < 0.05$.

RESULTS

A total of 116 healthy subjects (55 men, 61 women) agreed to participate in this study. Subjects were classified into three subgroups according to age (20-39 yrs, 40-59 yrs, ≥ 60 yrs). The number of individuals in age subgroups is shown in Table 1.

Table 1. The number of individuals according to age subgroups

	20-39 yrs	40-59 yrs	≥ 60 yrs	Total
Male (n)	20	20	15	55
Female (n)	22	23	16	61
Total	42	43	31	116

The balloon expulsion time according to gender was determined as 44.1 ± 19.0 seconds in males and 56.4 ± 21.4 seconds in females ($t = -3.28$, $p = 0.001$). There was an increase in the balloon expulsion time in conjunction with increasing age in males ($KW_x = 23.3$, $p = 0.00001$) (Table 2), whereas no statistically significant difference in the balloon expulsion time was determined in conjunction with age in females ($KW_x = 0.44$, $p = 0.80$) (Table 3). There was a significant correlation between age and balloon expulsion time ($p = 0.0001$, $r = 0.352$) for the whole study group.

Table 2. Balloon expulsion times according to age subgroups in men

Age group	Mean (sec)	N	Std. Deviation	Minimum	Maximum	Mean Rank
20-39	58.6	22	25.9	20	90	32.863
40-59	54.7	23	20.1	20	90	29.369
60+	55.9	16	16.8	17	90	30.781
Total	56.4	61	21.3	17	90	

sec: Second, std: Standard

Table 3. Balloon expulsion times according to age subgroups in women

Age group	Mean (sec)	n	Std. Deviation	Minimum	Maximum	Mean Rank
20-39	28.6	20	11.7	15	60	14.625
40-59	49.8	20	19.5	20	85	32.975
60+	57.1	15	11.2	35	83	39.2
Total	44.1	55	19.0	15	85	

sec: Second, std: Standard

DISCUSSION

To our knowledge, no data are available on normative values of the balloon expulsion test in healthy Turkish subjects. In this study, the balloon expulsion time was found lower than 2 minutes, mean 44.1 ± 19.0 seconds in men and 56.4 ± 21.4 seconds in women. It has been demonstrated that it should be less than 30 seconds for men younger than 40 years of age, and less than 1 minute above 40 years. For women, it should be 1 minute regardless of age. The major goal of this study was to determine the normative values in a large cohort of healthy individuals compared to other published reports. A few studies with small sample size are available in the literature evaluating the normal values of this test in healthy subjects (5,8-11). In detailed evaluation of anorectal functions in 45 healthy American adults, it was reported that balloon expulsion time was 42 ± 51 for < 50 yrs and 78 ± 96 for > 50 yrs in men and 64 ± 61 for < 50 yrs and 51 ± 71 for > 50 yrs in women. Our results are comparable with these values (8) with slightly shorter time frames in men.

The major limitation is that the methodology of the balloon expulsion test has not been standardized. In our study, we used a commercially available standard latex balloon with fixed volumes of 60-ml air and asked the subjects to expel the balloon in a sitting position. In other reports, several techniques were used, including 25 ml (10) or 50 ml balloons (8-10, 12), 10 cm condoms (7), 18 mm spheres (10), a silicon-filled and barium-coated artificial stool (fecom) (13), or weights attached to a pulley to assess the extra force required to expel a metal sphere in the lying position (14). Some authors have recommended that the balloon be filled with water or air until the subject reports a desire to defecate, since a sustained feeling of defecation is necessary to start the defecatory maneuver (7, 15). In contrast, most studies have used balloons with fixed volumes (50 or 60 ml) of water or air (8-12, 16). We consider that using a latex or party balloon with a fixed volume of water or air is more convenient in clinical practice. Furthermore, the upper limit for the time taken by a subject to expel the balloon in order to categorize the test as abnormal has either been variable or not defined. Some have used greater than 1 minute (7) and others 5 minutes (10, 12) as the upper limit for abnormal testing. According to our results, the upper limit should be less than 1 minute for men and 1.5 minutes for women.

The balloon expulsion test is one of the diagnostic workups of functional defecation disorders in the Rome III criteria. Rao (6) has recommended that the inability to expel a balloon or stool-like device such as a fecom within 3 minutes must be considered as one of the physiologic criteria of dyssynergic defecation. A recent systematic review showed that nine relevant studies were available in English literature from Western countries for the balloon expulsion test in the diagnostic evaluation of patients with functional constipation (17). Barnes *et al.* (9) compared their results between 39 constipated patients and 15 healthy volunteers. They showed that from among 21 constipated patients who had nonrelaxation of the sphincter during straining in defecography, 12 (57%) were unable to expel a water-filled balloon. A recent report showed that in 35 patients with constipation, 89% of patients (16/18) with obstructive defecation were unable to expel a 50 ml water-filled balloon, compared with 23% of patients (4/17) with nonobstructive constipation and four (16%) normal subjects (5). Minguez *et al.* (7) evaluated the predictive value of the balloon expulsion for diagnosing pelvic floor dyssynergia. In this study, an empty 10-cm-long latex condom was filled with warm water (36°C) until inducing a sustained desire to defecate and the test was considered normal if the balloon could be expelled within 1 minute. The balloon expulsion test was found abnormal in 21 of 24 patients with pelvic floor dyssynergia and 12 of 106 patients with functional constipation (without dyssynergia). The authors reported that the specificity and negative value of the test for excluding pelvic floor dyssynergia were 89% and 97%, respectively. In accordance with these results, patients with a normal expulsion test result independent of the frequency of symptoms do not need other functional studies, which are more expensive and difficult to perform, to rule out obstructive defecation. This suggests that a normal test would at least exclude dyssynergia. However, this observation is confounded by other studies in which many patients with dyssynergia could expel the balloon (18), and this test alone was insufficient to make a diagnosis of dyssynergia. In fact, a poor positive predictive value of this test (64%) has been reported (7).

None of the subjects was unable to expel the balloon in our study group, which is similar to results

shown by others (10, 11). The prevalence of difficulty with evacuating balloons in healthy controls has been reported as 0-16% (5, 8-11). Rao *et al.* (8) revealed that 41 of 45 healthy subjects (91%) were able to expel a 50 cc water-filled balloon while four subjects could not. Another study showed that all normal subjects who could not expel a balloon (4 of 25 healthy subjects) had a low defecation index, but only one showed an obstructive pattern of defecation (5). It has been reported that up to 20% of normal individuals may exhibit an obstructive pattern of defecation (5, 19), and in some subjects there is a poor correlation between obstructive pattern, bowel habit, and ability to expel a simulated stool. Because other anorectal functional tests were not performed in our healthy group, we are unable to describe how many of our normals would meet the criteria for obstructive defecation.

In the results of our study, although all participants evacuated the balloon in less than 2 minutes, balloon expulsion time was longer for women than men. Some studies have reported that the balloon expulsion time was similar between men and women in healthy subjects (8, 11). This difference may be due to the smaller size of their population. There was also a positive correlation between age and time of evacuation. This correlation was statistically significant in men but not in women. Some studies have demonstrated that men had a higher defecation index (DI) than women. Older men also had a lower DI and took a longer time to expel a balloon (8), which suggests that aging might be associated with impairment of pelvic floor function, at least in men [DI: this index has been used as an overall measure of the coordinated effort between the rectum and the anus and can be calculated from the equation: rectal pressure when straining ÷ anal residual pressure when straining (5, 18)].

In conclusion, the balloon expulsion test is a simple procedure to establish impaired evacuation in constipated patients and has been recommended as one of the Rome III diagnostic criteria for functional defecation disorders. It is possible to use the test in primary health care centers. Our results may serve as a useful source of normative data in a healthy population.

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