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ORIGINAL ARTICLE

The use of pediatric fall risk assessment tool in gastrointestinal endoscopic procedures: A prospective study

Gastrointestinal endoskopik prosedürlerde pediatrik düşme riski değerlendirme aracının kullanımı: Prospektif bir çalışma

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Background and Aims: The aim of this study is to evaluate the fall risk with Humpty Dumpty Fall Scale and determine related risk factors in pediatric patients undergoing gastrointestinal endoscopy. **Materials and Methods:** A prospective descriptive study was conducted in a large tertiary pediatric hospital. Patients' demographics, type of endoscopy, duration of endoscopic procedures, type of procedural sedation, doses of administered drugs during anesthesia, and post-procedure Humpty Dumpty Fall Scale scores were collected. Post-hoc and logistic regression analyses were performed to identify within-group differences and independent predictors of patient outcomes. **Results:** One hundred ninety-two pediatric patients (54.2% female) with a mean (standard deviation) age of 11.16 (5.32) years were admitted for a diagnostic gastrointestinal endoscopy. During procedures, the most commonly administered sedatives were midazolam (98.9%), propofol (96.9%), fentanyl (63.0%), and ketamine (34.9%). According to the Humpty Dumpty Fall Scale, 148 (77.1%) patients had a high risk for falls. No falls after endoscopic procedures was observed in the patients. When the predictive factors determining being at high-risk for falls were examined, the simultaneous application of esophagogastroduodenoscopy and colonoscopy under the same procedural sedation increases the risk of being high-risk 5.2 times compared to the performing esophagogastroduodenoscopy alone (p = 0.047). **Conclusion:** To the best of our knowledge, this is the first study evaluating the use of Humpty Dumpty Fall Scale to predict falls in pediatric patients undergoing gastrointestinal endoscopy with procedural sedation. Although 77.1% of the patients were found to be at high risk for falls, there was no fall event after the endoscopic procedures due to precautionary measures. Our results indicate that pediatric patients undergoing gastrointestinal endoscopy with sedation are at increased risk of falling and preventive measures should be taken.

Key words: Humpty Dumpty Fall Scale, fall risk, esophagogastroduodenoscopy, colonoscopy, sedatives, children

Giriş ve Amaç: Bu çalışmanın amacı endoskopi işlemi uygulanan çocuk hastalarda Humpty Dumpty Düşme Ölçeği ile düşme riskini ve düşme riskini etkileyen faktörleri belirlemektir. **Gereç ve Yöntem:** Prospektif tanımlayıcı özellikteki bu çalışma büyük bir üçüncü basamak pediatri hastanesinde yapıldı. Hastaların demografik özellikleri, endoskopi tipi, endoskopik işlemlerin süresi, uygulanan sedasyonun tipi, anestezi sırasında uygulanan ilaçların dozları ve işlem sonrası Humpty Dumpty Düşme Ölçeği skorları ile ilgili veriler toplandı. Grup içi farklılıkları ve hasta sonuçlarını etkileyen bağımsız faktörleri belirlemek için post-hoc ve lojistik regresyon analizleri yapıldı. **Bulgular:** Ortalama (standart sapma) yaşları 11.16 (5.32) olan 192 pediatrik hastaya (%54.2'si kız) tanısal gastrointestinal endoskopi yapıldı. İşlemler sırasında en sık uygulanan sedatifler midazolam (%98.9), propofol (%96.9), fentanil (%63.0) ve ketamin (%34.9) olarak saptandı. Humpty Dumpty Düşme Ölçeği'ne göre 148 (%77.1) hasta düşme açısından yüksek riske sahipti. Hastaların hiçbirinde endoskopik işlemler sonrası düşme gözlenmedi. Düşme açısından yüksek riskli olmayı belirleyen prediktif faktörler incelendiğinde, aynı prosedürel sedasyon altında özofagogastroduodenoskopi ve kolonoskopinin eş zamanlı olarak uygulanmasının, sadece özofagogastroduodenoskopi uygulamasına kıyasla düşme açısından yüksek riskli olmayı 5.2 kat artırdığı görüldü (p = 0.047). **Sonuç:** Bildiğimiz kadarıyla bu çalışma, Humpty Dumpty Düşme Ölçeği'nin prosedürel sedasyon altında gastrointestinal endoskopi yapılan pediatrik hastalarda düşme riskinin öngörülmesinde kullanılmasını değerlendiren ilk çalışmadır. Hastaların %77.1'i düşmeler açısından yüksek riskli bulunmasına rağmen, alınan önlemler nedeniyle endoskopi işlemlerinden sonra herhangi bir düşme olayı yaşanmamıştır. Sonuçlarımız, sedasyon altında gastrointestinal endoskopi yapılan pediatrik hastaların düşme riskinde artış olduğunu ve mutlaka önleyici tedbirler alınması gerektiğini göstermektedir.

Anahtar kelimeler: Humpty Dumpty Düşme Ölçeği, düşme riski, özofagogastroduodenoskopi, kolonoskopi, sedatifler, çocuklar

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INTRODUCTION

For decades, inpatient healthcare facilities have focused on the prevention of falls and the injuries that they cause, but little is known about the variables that predict falls in outpatients undergoing gastrointestinal endoscopy procedures (1). Pediatric patients are at higher risk for both falling and serious complications associated with falls. Falls ranked third among the most commonly reported incident types after 'medication' and 'clinical deterioration' (2). According to the Parker et al.'s analysis of falls in a pediatric hospital, outpatient falls accounted for 24.9% of total falls, with falls occurring in only 0.02% of outpatient presentations (3). The vast majority of children who have unintentional falls were discharged home, and mortality was extremely rare. However, younger ages are more susceptible to more severe injury patterns (4). Intracranial hemorrhage and thoracic injury are risk factors necessitating long-term medical care (5). While these estimates suggest that fall-related serious morbidity rates are generally low, the actual number of pediatric falls is likely to be underestimated because non-injury fall incidents are unlikely to be reported (6). For this reason, the Humpty Dumpty Fall Scale (HDFS) was created in 2005 to address an unmet need by identifying the pediatric population at risk of a fall event. This risk scale is now used in over 1500 institutions on six continents and has been translated into 15 languages. The HDFS is globally used and accepted as the most effective scale to detect and prevent fall risk (7). The tool is divided into parameters based on age, gender, diagnosis (neurological, alterations in oxygenation, psych/behavioral, and other disorders), cognitive impairments, environmental factors, response to surgery/sedation/anesthesia, and medication usage (sedatives, hypnotics, barbiturates, phenothiazines, antidepressants, laxatives/diuretics, and narcotics). Each of these sections receives a score, and the total of all parameter scores is tabulated (min-max: 7-23 points). A score of 12 or above is considered high risk and necessitates the implementation of a protocol to protect the patient (8). Although several of the HDFS items are significantly associated with the risk of falls in the pediatric population, the predictive validity, specificity, and internal consistency of the HDFS are concerning in the pediatric population (9).

The aim of this study was to evaluate the fall risk with HDFS and determine related risk factors in pediatric patients undergoing gastrointestinal endoscopy.

MATERIALS and MTHODS

Data Collection and Sample Characteristics

In this prospective, single-center cohort study, children aged 0-18 years, for whom a diagnostic endoscopy procedure [Esophagogastroduodenoscopy (EGD) and ileocolonoscopy (IC)] was scheduled by a pediatric gastroenterologist, were included in the study for one year. Patients' age, gender, weight, diagnosis, type of endoscopic procedure, duration of the procedures, type of procedural sedation, doses of administered drugs during anesthesia, and post-procedure HDFS scores were collected. International Classification of Diseases 10th Revision (ICD-10) codes for diagnoses, Anatomical Therapeutic Chemical (ATC) codes for categorization of drugs were used for all patients. Combined sedatives were administered according to the patient's clinical condition, sedation response, and duration of the procedure by the anesthesiologists. Total doses administered during the procedure were recorded. The Institutional Review Board of Hacettepe University approved this study (GO21-359, 12/09/21) and written informed consent/assent was obtained from each parent/legal guardian of the participant and the patients aged ≥13 years.

Sedatives administered to patients throughout the procedures were midazolam, propofol, fentanyl,

and ketamine. *IBM Micromedex® Pediatrics Drug Monograph* (10) was used to determine the minimum effective doses of each agent. The number of patients who were administered sedatives above the minimum effective dose was determined according to this database. Thus, it was aimed to determine the sedative effect of each drug and its effect on the fall risk. In addition, other drugs administered to the patients during ambulatory care were also questioned.

Data Analysis

Firstly, it was planned to reach nearly 165 patients within the stipulated timeframe (during one year), with an effect size of 0.25, a power of 95%, and a margin of error of 5% *(G* Power 3.1 Statistical Power Analysis)*. The normality of continuous variables was tested using the Shapiro–Wilk test. After data extraction, continuous variables were defined as the mean ± standard deviation (SD) and median (range), depending on the result of normality test. Categorical and numerical variables were compared using the $\chi 2$ and independent sample T-test or Mann-Whitney U test. Also, post-hoc analysis was used to identify within-group differences. For the binary logistic analysis, the possible factors identified in univariate analyses were further entered into the logistic regression analysis to determine independent predictors of patient outcome. Hosmer-Lemeshow goodness of fit statistics was used to assess model fit. For all tests, $p<0.05$ was considered statistically significant. All analyses were carried out in the *IBM SPSS Statistics Version 23 software.*

RESULTS

During the study period, 192 endoscopy sessions were included. One-hundred-four (54.2%) of the 192 patients were female, and single EGD was performed on 113 (58.9%) patients. The most common diagnoses were inflammatory bowel disease (18.2%) and celiac disease (15.6%). The mean procedure time (SD) for each patient was 27.6 (18.54) minutes. While the median (range) total number of sedatives administered during the procedures was 3 (1-4), the most commonly administered sedatives were midazolam (98.9%), propofol (96.9%), fentanyl (63.0%), and ketamine (34.9%). The most commonly used combination of sedatives during the procedures were midazolam + propofol + fentanyl (39.6%), midazolam + propofol + fentanyl + ketamine (22.9%), and midazolam + propofol (21.9%). According to the *Micromedex®* dosing guidelines for monotherapy, the ratio of patients in whom midazolam, propofol, fentanyl, and ketamine were administered above the minimum effective dose were, 23.4%, 30.7%, 32.3%, and 17.7%, respectively (Table I). There was no medication history (hypnotics, barbiturates, phenothiazines, antidepressants, laxatives/diuretics, and narcotics) causing clinically significant drug-drug interaction with sedatives. No falls were observed during and immediately after the endoscopy procedure. The patients were accompanied by a nurse and/or a doctor (anesthetist or gastroenterologist) until they were taken to the observation room as per institution protocol. The patients were also monitored for a certain period of time following the procedure. When the patients were evaluated with HDFS after the endoscopic procedure, the median (range) score was 12 (7-20). According to the HDFS taking cut-off value as 12 points, 44 (22.9%) of the patients had a low risk for and 148 (77.1%) had a high-risk for a fall (Table 2).

When comparing low- and high-risk groups for HDFS, midazolam per kg (mean difference: 0.024, $p = 0.017$) and propofol per kg (mean difference: 0.856, $p = 0.042$) doses were found to be statistically higher in high-risk patients than in low-risk patients. According to the $\chi 2$ test, there was a significant relationship among the type of endoscopy ($p = 0.042$) and fentanyl administration ($p = 0.040$)

Table 1 Patient characteristics (n = 192)

Variables	
Gender, female, n (%)	104 (54.2)
Age, years, mean (SD)	11.16 (5.32)
Weight, kg, mean (SD)	38.81 (19.88)
Diagnosis, n (%)	
Other diseases of the digestive system	50 (26.0)
Inflammatory bowel disease	35 (18.2)
Celiac disease	30 (15.6)
Liver diseases	26 (13.5)
Malignancy or suspicion for malignancy	11 (5.7)
Suspicious allergic reaction	9 (4.7)
Others	31 (16.1)
Type of endoscopy, n (%)	
EGD	113 (58.9)
EGD + IC	57 (29.7)
IC	20 (10.4)
Rectoscopy	2 (1.0)
Duration of the procedure, minutes, mean (SD)	27.67 (18.54)
Total number of sedatives, median (range)	3 (1-4)
Midazolam, n (%)	190 (98.9)
Midazolam dose, mg, median (range)	3 (1-6)
Midazolam dose, mg/kg, median (range)	0.07 (0.02 - 0.21)
Administration above the minimum effective dose, n (%)	45 (23.4)
Propofol, n (%)	186 (96.9)
Propofol dose, mg, median (range)	60 (10 - 300)
Propofol dose, mg/kg, median (range)	2.09 (0.28 - 8.33)
Administration above the minimum effective dose, n (%)	59 (30.7)
Fentanyl, n (%)	121 (63.0)
Fentanyl dose, mcg, median (range)	25 (5-170)
Fentanyl dose, mcg/kg, median (range)	0.75 (0.39 - 2.78)
Administration above the minimum effective dose, n (%)	62 (32.3)
Ketamine, n (%)	67 (34.9)
Ketamine dose, mg, median (range)	20 (5 - 60)
Ketamine dose, mg/kg, median (range)	0.56 (0.13 - 2.79)
Administration above the minimum effective dose, n (%)	34 (17.7)
Combination Sedatives (n = 186), n (%)	
Midazolam + Propofol + Fentanyl	76 (39.6)
Midazolam + Propofol + Fentanyl + Ketamine	44 (22.9)
Midazolam + Propofol	42 (21.9)
Midazolam + Propofol + Ketamine	22 (11.5)
Midazolam + Fentanyl	1 (0.5)
Midazolam + Ketamine	1 (0.5)

SD: Standard deviation, EGD: Esophagogastroduodenoscopy, IC: Ileocolonoscopy

with the HDFS category. However, no significant differences were detected when the total HDFS scores were compared amongst all types of endoscopic procedures with post-hoc analysis ($p > 0.05$). Conversely, a statistically significant difference was found when the total HDFS scores of the patients who received (n = 71, HDFS: 14.03) and did not receive (n = 121, HDFS: 12.69) fentanyl were compared ($p = 0.007$). Finally, when the predictive factors determining the high-risk for falls were examined, the simultaneous application of EGD and ileocolonoscopy under the same procedural

Table 2 Scoring for The Humpty Dumpty Fall Scale in the study population

Parameter	Score (circle)	Number of Patients, N (%)
Age, n (%)		
<3 years old	4	20 (10.4)
3-7 years old	3	31 (16.1)
7 - 12 years old	2	54 (28.1)
13 years and above	1	87 (45.3)
Gender, n (%)		
Male	2	88 (45.8)
Female	1	104 (54.2)
Diagnosis, n (%)		
Neurological diagnosis	4	5 (2.6)
Alterations in oxygenation	3	5 (2.6)
Psych/Behavioral disorders	2	10 (5.2)
Other diagnosis	1	172 (89.6)
Cognitive impairments, n (%)		
Not aware of limitations	3	28 (14.6)
Forgets limitations	2	16 (8.3)
Oriented to own ability	1	177 (78.1)
Environmental factors, n (%)		
History of falls or infant-toddler placed in bed	4	8 (4.2)
Patient uses assistive devices or infant-toddler crib	3	12 (6.3)
Patient placed in bed	2	18 (9.4)
Outpatient area	1	154 (80.2)
Response sedation, n (%)		
Within 24 h	3	189 (98.4)
Within 48 h	2	-
> 48 h	1	3 (1.6)
Medication usage, n (%)		
Multiple uses of sedatives/hypnotics/barbiturates	3	186 (96.9)
One of the medications listed	2	4 (2.1)
Other medications or none	1	2 (1.0)
Total HDFS Score, median (range)		12 (7 - 20)
Category of HDFS Score, n (%)		
Low-risk (7 - 11 points)		44 (22.9)
High-risk (12 or above points)		148 (77.1)

HDFS: The Humpty Dumpty Fall Scale.

sedation increases the risk of being high-risk 5.2 times (95% CI 1.020 - 26.718, p = 0.047) compared to the application of EGD alone (p-value for Hosmer-Lemeshow test = 0.878).

DISCUSSION

To the best of our knowledge, this is the first study evaluating the use of HDFS to predict falls in pediatric patients undergoing gastrointestinal endoscopy with procedural sedation. Although 77.1% of the patients were found to be at high risk for falls, there was no fall event after the endoscopic procedures due to precautionary measures. Predicting falls in pediatric inpatients and outpatients undergoing procedural sedation remains challenging. The causes of falls are accompanied by many dynamic factors including the patient's demographic and clinical characteristics, healthcare system policy of hospitals, and medication history (11-13). Although the fall risk is evaluated by nurses in hospitalized pediatric patients, this assessment can be neglected in pediatric populations undergoing procedural sedation such as gastrointestinal endoscopy.

According to a review of instruments for assessing the risk of falls in pediatrics, the HDFS was the most utilized compared to other pediatric fall risk assessment tools such as The Generalized Risk Assessment for Pediatric Inpatient Falls (GRAFPIF), CUMMINGS, I'M SAFE, and CHAMPS (14). However, markedly low specificity (high false-positive rate) of HDFS is problematic and causes 80% of studied children to be classified as high-risk taking a cut-off score of 12 (9,15-17). Therefore, in this study, we moved away from the general pediatric inpatient population and included only patients undergoing a gastrointestinal endoscopic procedure with procedural sedation in the ambulatory care. Recently, Sarik et al. (7) improved HDFS by removing two parameters (gender and medication use) from the scoring algorithms. In that study, the modified scale demonstrated slightly higher sensitivity (84% vs 71%) and specificity (57% vs 54%) compared to the original HDFS scoring. In contrast to their findings, we found that sedative agents and their doses administered during endoscopy may influence the fall risk. Patients in high-risk group received higher doses of midazolam and propofol. Also, patients who were administered fentanyl had higher HDFS scores than those who were not administered this medication. Based on these results, we believe that some additional reflections on a new scale that separately evaluates each sedative and its dosing after procedural sedation are needed. Cognitive impairment (behavioral issues, lack of insight, etc.) also plays a major role in pediatric falls. In a cross-sectional study, HDFS total mean score correlates negatively with age, gender, and intelligence quotient in children with neurological and neurodevelopmental conditions (18). Similarly, in our study, the cognitive functions of almost a quarter of the patients were determined as "forget limitations" or "not aware of limitations".

According to a study that retrospectively reviewed HDFS scores using electronic medical records, 65% of the controls were misclassified as at high risk, indicating a very large number of false positives (patients identified as likely to fall) (19). Similarly, in another retrospective study, more than two thousand children were evaluated with HDFS and the median total HDFS score was found to be 13 in both patients with and without a fall (9). In our prospective study design, there were no falls in patients who were determined as high-risk which represents 77.1% of the study population. However, all patients in our study were under close monitorization by a nurse and/or a doctor immediately after the procedure as per institution protocol. We also use a safety belt for proper and safe positioning of the patient during endoscopy. These precautionary measures may have prevented the falls in our study cohort.

It is possible to predict the probability of falls by obtaining relevant information from parents. Therefore, pediatric nurses should implement fall education by accurately and consistently identifying parents' knowledge of hospital-acquired falls. Also, implementing pediatric-specific, evidence-based interventions can help to reduce the true incidence of pediatric patient falls (20). We recommend that parents' and nurses' education should be improved regarding examining the risk factors of children who will be administered procedural sedation before procedures such as gastrointestinal endoscopy. Comprehensive protocols help to guide interventions to reduce fall risk based on a patient's total fall risk score. The use of HDFS and subsequent interventions may result in changes in patient care and, most likely, behavioral changes in nurses, which may reduce the likelihood of a patient's fall experience (Table 3).

Table 3 Standard protocol for low and high risks after Humpty Dumpty Fall Scale implementation (9)

Low-Risk Standard Protocol (Score 7 - 11)
Orientation to room
Bed in a low position, brakes on
Side rails × 2 or 4 up; assess large gaps such that a patient could get extremity or other body part entrapped; use additional safety procedures
Use of nonskid footwear for ambulating patients; use of appropriate-size clothing to prevent the risk of tripping
Assess eliminations need; assist as needed
Call light is within reach; educate patient/family on its functionality
Environment clear of unused equipment, furniture in place, clear of hazards
Assess for adequate lighting; leave a nightlight on
Patient and family education available to parents and the patient
Document fall prevention teaching and include it in the plan of care
High-Risk Standard Protocol (Score 12 and Above)
Identify the patient with a "Humpty Dumpty" armband on the patient (if ambulatory) and "Humpty Dumpty" sign at the head of the bed or crib
Educate patients/parents on falls protocol precautions
Check the patient a minimum of every 1 h
Accompany the patient during ambulation
Developmentally place the patient in an appropriate bed
Consider moving the patient closer to the nurses' station
Assess the need for 1:1 supervision
Evaluate medication administration times
Remove all unused equipment from the room
Protective barriers to close off spaces, gaps in the bed
Keep the door open at all times unless specified isolation precautions are in use
Keep the bed in the lowest position, unless the patient is directly attended
Document in the Patient Education section of the electronic health record and on High Risk for fall care plan

Even though the targeted sample size was reached and the study was conducted in a prospective design to obtain real-life data in the study population, this study has some limitations. The data obtained from a single-center limit the heterogeneity of the data pool. Furthermore, we could not determine the performance of the HDFS due to the lack of fall events in this specific study population. Also, limitations inherent to the tool itself may have contributed to bias regarding predicting fall risk.

To the best of our knowledge, this is the first study evaluating the use of Humpty Dumpty Fall Scale to predict falls in pediatric patients undergoing gastrointestinal endoscopy with procedural sedation. Although 77.1% of the patients were found to be at high risk for falls, there was no fall event after the endoscopic procedures due to precautionary measures. Our results indicate that pediatric patients undergoing gastrointestinal endoscopy with sedation are at increased risk of falling and preventive measures should be taken. Regarding medications, sedative agents and their doses administered during the endoscopy may have an effect on the fall risk. Future research should concentrate on developing new and specific scales that examine sedatives and their doses in detail and include the type of endoscopy to determine the fall risk in pediatric patients undergoing endoscopic procedures.

Ethics

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Hacettepe University (decision no: 2020/08-47, decision date: 17.04.2020).

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