ORIGINAL ARTICLE

Predictors of high-risk unscheduled return visits to the pediatric emergency department: a case-control study

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ABSTRACT

Background and Objective: High-risk unscheduled return visits (HRURVs) are a key quality metric in the Emergency Department (ED). We, therefore, aimed to determine their incidence and clinical predictors in the pediatric ED.

Design: This is a case control study.

Setting: This study was conducted in the pediatric ED of an Eastern Mediterranean tertiary care hospital.

Participants: Cases included HRURVs ≤18 years old that presented to the ED between November 1, 2014, and October 31, 2015. Controls included patients discharged from the ED during this period and who did not return within 72 hours. Controls were matched 1:1 based on age, gender and date of presentation (±7 days). Out of 14,805 Pediatric ED visits, 142 were HRURVs, with an incidence of 0.96% [95% confidence intervals (CI) 0.81 to 1.13]. Our final analysis included 139 HRURV cases and 139 controls. 3 were excluded because of incomplete charts.

Main Outcome Measures: The outcome, HRURV was defined as an ED return visit within 72 hours that required admission or died in the ED.

Results: Of the cases, 2.6% were admitted to the intensive care unit and 7.19% required surgical intervention. Cases were more likely to be hospitalised in the last 30 days [adjusted odds ratio (AOR) 19.53, 95% CI 2.45 to 155.44], have more laboratories ordered (AOR 3.74, 95% CI 2.15 to 6.48), present with a temperature > 38.5°C (AOR 2.63, 95% CI 1.26 to 5.48) and have a discharge diagnosis related to the digestive system (AOR 1.96, 95% CI 1.04 to 3.72). Receiving at least one medication at the index visit was a negative predictor (AOR 0.35, 95% CI 0.19 to 0.63).

Conclusion: Efforts to reduce HRURVs should focus on the clinical predictors identified. Receiving medications in the ED appears to be protective requiring further research to identify medication categories driving this finding.

Keywords: Emergency Department, high-risk unscheduled return visits, bounceback, pediatrics.

Introduction

Background

The Emergency Department (ED) is typically a high acuity setting, with a constant flow of new patients, with whom the treating physician does not usually follow up after discharge. This busy, high risk environment may put the patient at risk of adverse outcomes [1,2]. Therefore, measures have been implemented and indicators used to minimise these at different levels [3]. Unscheduled Return Visits (URVs), defined as a return visit to the

ED within 72 hours from the index ED visit, have been extensively studied in adults and are used as an indicator of the quality of care [4]. In the pediatric population,

the American Academy of Pediatrics and the United Kingdom Department of Health advocate its use as a quality indicator with target rates of 1% to 5% [5,6]. Yet, the use of URVs as a quality indicator has recently come under scrutiny with some studies finding no association with increased mortality and reports of main causes pointing to the progression of disease, parental concern or non-compliance with care rather than system or physician errors [7]. The former, such as parental concerns and non-compliance with instructions, can be avoided with specific interventions [8].

One subgroup of high-risk URVs (HRURVs), defined as URVs resulting in hospital admission or ED death, may re-present to the ED sicker, and thus requires special consideration. This is a specific group that may have needed admission at the index visit or further diagnostics or treatments to prevent the need for admission on the second visit. Therefore, understanding predictors of HRURVs is crucial to develop interventions to prevent them. Risk factors for pediatric URVs have already been described in the literature including high-acuity, younger age, comorbidities, and time of presentation [9-11]. However, few studies have focused on HRURVs and most were limited by retrospective review design and did not include in-depth clinical characteristics [12,13].

The primary objective of this study was to determine the incidence and predictors of HRURVs in the pediatric population of a Lebanese ED, in order to guide future quality initiatives.

Methods

Study design

We conducted a retrospective case-control study of patients 18 years of age or younger. HRURVs were defined as patients who represented to the ED within 72 hours of discharge from the first visit, with the same complaint or concern, and were admitted to the hospital or died in the ED. The study protocol was approved by the Institutional Review Board of the American University of Beirut.

Setting

This study was conducted at the Department of Emergency Medicine (EM) at the American University of Beirut Medical Center (AUBMC). AUBMC is a tertiary care, teaching hospital with 384 beds. The ED is one of the largest in the country, with around 54,000 patient visits annually, of which 14,500 (27%) are 18 years and less. It is divided into three areas: high acuity, low acuity and pediatrics. The pediatric section of the ED is staffed by a mix of EM physicians and non-EM physicians (pediatricians and family physicians) with extensive experience in the ED. While ED staffing is based on historical ED visit hourly load, ancillary and consultant service staffing drops to off-hour level between 17:00 and 08:00. We use the Emergency Severity Index (ESI) score in triage to stratify our patients into five different acuity levels, from the most urgent (1) to the least urgent (5) based on acuity and resources needed. Most of our ED pediatric patients (87.4%) are triaged to an ESI score

of 3 (intermediate acuity), 5.3% have an ESI of 4-5 (low acuity) and 6.6% have an ESI of 1-2 (high acuity). Around 85% of pediatric patients are insured, while 15% payout of pocket. The hospital admission rate for pediatric ED patients is 11% and in ED mortality for the pediatric population is 0.3/1,000 and includes all out of hospital cardiac arrests. The pediatric critical care admission rate is around 3.5% in our ED.

Patient and public involvement

This study was designed, the data analysed and interpreted, and the manuscript written without patient or public involvement. Patients were not consulted for patient-important outcomes.

Selection of participants

Figure 1 shows the selection process of cases and controls. Cases included all HRURVs 18 years or younger who presented to the ED between November 1, 2014, and October 31, 2015. We defined HRURVs as patients who returned to the ED within 72 hours and were admitted or died on a return visit. We excluded patients who were discharged from the ED on 72 hours return. We also excluded patients who: returned with complaints unrelated to the initial visit, were transferred to another facility, left without being seen had an incomplete visit (left the ED after initial screening by a physician without informing the ED team) or had a scheduled ED visits. The latter, in our setting, is limited to scheduled visits for wound checks or referrals related to abnormal laboratory findings. Double entries and missing charts were also excluded. Furthermore, if a case had several encounters during the study period, we counted the patient only once to reduce bias in our sample. This encounter was chosen based on the visit that had the most complete medical record.

Cases were matched to controls by age (±1 year), gender and admission date (±7 days). Eligible controls included ED visits during the same time period that did not return within 72 hours and were discharged home. If a case was matched to multiple controls, we selected the control whose date of presentation was closest to the date of presentation of the case. If there were multiple possibilities, we chose the control with the most complete medical record. Once the control was selected for a particular case, that control was removed from the pool for the rest of the cases.

Methods of measurements

Data were extracted from an ED administrative database and medical record charts. To facilitate data extraction from the medical records charts, a data collection sheet with the de-identified cases and controls was used and then merged with the administrative data. Two trained research assistants (medical doctors) blinded to the study objectives reviewed the patient medical records for inclusion criteria and extraction of all clinical data. The primary investigator made the final decision on the exclusion of cases for unrelated visits. Clinical data were extracted from the chart review and included vital signs on presentations and interventions
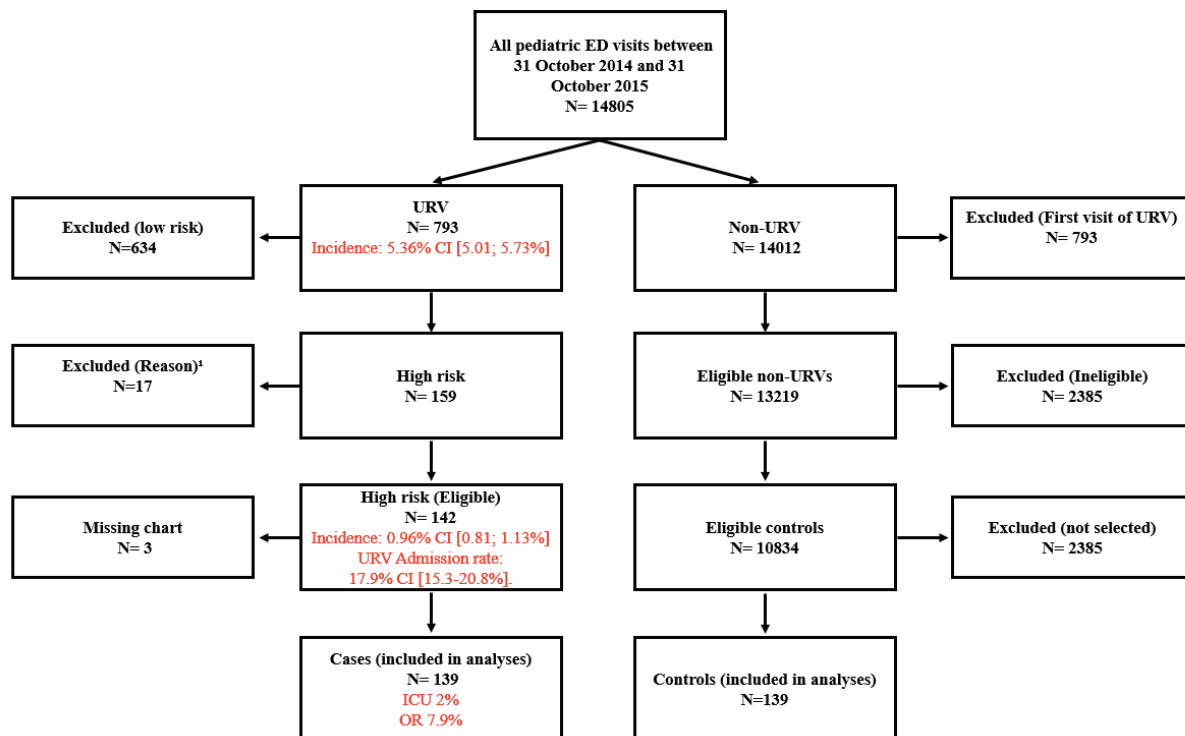
Figure 1. *Flow chart showing the selection process of cases and controls.*

Reason¹: second visit unrelated to initial visit, patient discharged on second visit, double entry, empty file, patient's first visit does not fall under the study period, admitted on both mentioned dates, called back for lab study abnormalities. 6 cases had two HRURV during the study period and therefore six encounters were excluded in the reason (out of 17).

ED = Emergency Department; URV = Unscheduled return visit; HRURV = High risk unscheduled return visit; ICU = Intensive care unit; OR = Operating room.

in the ED including diagnostics, consults, medications administered, procedures undergone and surgical interventions on admission to the hospital.

The administrative database was used to extract socio-demographic data, frequency of past-ED visits, ED volume (total number of ED visits on date of case-control visit, calculated for each patient visit separately, as a measure of ED crowdedness), ESI, time measures and patient disposition. The International Classification of Diseases, Ninth Revision discharge diagnosis was further classified into 25 Major Diagnostic Categories to collapse the data into more manageable categories.

Off-hour visits included all weekend visits and visits between 17:00 and 8:00 hours on weekdays. A handover is a situation where the patient's ED stay overlapped with at least two ED medical provider shifts. Therefore, the care was provided by at least two different supervising physicians during the same ED visit. We considered that a handover took place if, during the index visit, the name of the admitting provider was different from the discharging provider in the medical records. Normal ranges of heart rate and respiratory rate were based on the age of the patient and retrieved from a systematic review of observational studies [14].

Finally, incidence of URV and HRURV was defined as the total number of URVs and HRURVs, respectively, divided by the total number of ED visits during the study period.

Analysis

Data were described as number and percent for categorical variables, whereas the mean and standard deviation (±SD) were calculated for continuous ones. Association between each of the predictors and the HRURV group was assessed by the Pearson Chi-square test for categorical variables, whereas the Student's *t*-test was used for continuous predictors. Moreover, multivariate stepwise logistic regression was carried out to identify the predictors of HRURV, where we entered any variable from the bivariate analysis with a *p*-value less than 0.05. Results are presented as adjusted odds ratio (AOR) and 95% confidence intervals (CI). A *p*-value less than 0.05 was used to indicate statistical significance. We used IBM SPSS statistical software for Windows version 22 (SPSS for Windows, version 22, SPSS, Inc., Chicago, IL).

Results

During the study period, 14,805 pediatric ED visits fit were identified, with a URV incidence of 5.36% CI (5.01% to 5.73%) and HRURV incidence rate of 0.96% CI (0.81% to 1.13%). The URV admission rate was 17.9% CI (15.3% to 20.8%) meaning that 139/793 URVs were HRURVs of which 2.6% (3/139) were admitted to the intensive care unit (ICU) and 7.19% (10/139) required a surgical procedure during their second visit (Figure 1). No return visit resulted in mortality.

Table 1. Index visit patient and ED characteristics.

	Cases N = 139 n (%)	Controls N = 139 n (%)	p-value
Gender			
Male	72 (51.8)	72 (51.8)	1.00*
Female	67 (48.2)	67 (48.2)	
Age (years), mean (±SD)	5.58 ± 5.55	5.58 ± 5.56	
<1 year	22 (15.8)	20 (14.4)	
1-4 years	59 (42.5)	61 (43.9)	
5-9 years	25 (18.0)	25 (18.0)	0.993*
10-14 years	16 (11.5)	16 (11.5)	
15-18 years	17 (12.2)	17 (12.2)	
Guarantor			
Insured	127 (91.37)	121 (87.05)	0.246
Self-paying	12 (8.63)	18 (12.95)	
Hospitalisation (past 30 days)	16 (11.51)	1 (0.72)	< 0.005
Number of ED visits (past year) mean (±SD)	1.27 ± 1.70	0.82 ± 1.37	0.016
0	60 (43.17)	79 (56.83)	
1	40 (28.78)	35 (25.18)	
2	14 (10.07)	13 (9.35)	0.057
3+	25 (17.99)	12 (8.63)	
ED characteristics			
LOS (hours) Mean ± SD	2.76 ± 1.82	1.80 ± 2.09	<0.0005
ED volume/day mean ± SD	146.89 ± 19.32	145.85 ± 18.38	0.664
Off-hour visits	103 (74.1)	102 (73.38)	0.892
Handover	28 (21.21)	17 (12.32)	0.050
AMA	6 (4.32)	3 (2.16)	0.501

The age groups are not identical between cases and controls among the youngest two age groups as an infant <1-year-old may have been matched to a child a few months older, putting them in the 1-4 group.

SD = Standard deviation; ED=Emergency Department; LOS = Length of Stay; AMA=Against medical advice.

*Matching characteristics.

Table 1 presents patient and ED characteristics for the index visit. We have grouped the ages into the following categories: less than 1-year-old, from 1 to 4 years old, from 5 to 9 years old, from 10 to 14 years old, and finally from 15 to 18 years old as this distribution has already been used in another pediatric study assessing pediatric ED visits in the Lebanese setting [15]. Cases had a significantly higher number of ED visits within the year prior (mean of 1.27 visits ± 1.70 vs. 0.82 visit ± 1.37, $p = 0.016$) and were more likely to have been hospitalised within the 30 days prior to the index visit (16/139 vs. 1/139, $p < 0.005$) than controls. Although the ED length of stay (LOS) in hours, defined as time from ED registration to ED discharge was significantly associated with HRURV (2.76 hours ± 1.82 vs. 1.80 hours ± 2.09; $p < 0.0005$), measures of ED crowdedness (i.e., ED volume/day) were not found to be significantly different ($p = 0.664$). Cases were not more likely to have presented on "off-hours" ($p = 0.892$) nor to have had a handover during their stay ($p = 0.050$).

In the bivariate model (Table 2), we compared patient clinical characteristics and ED managements decisions. We found that cases were more likely than controls to present to the ED tachycardic (112/139 vs. 94/139, $p = 0.01$), febrile (37/139 vs. 16/139, $p = 0.001$) and tachypneic (51/139 vs. 45/139, $p = 0.024$).

In addition, cases were more likely to have had laboratory testing done in the ED (96/139 vs. 51/139; $p < 0.0005$). Acuity and discharge diagnosis were both found to be statistically significant variables ($p = 0.05$ and 0.001 respectively). Interestingly, receiving at least one medication, irrespective of the mode of administration, in the index visit was a negative predictor for HRURVs (35/139 vs. 57/139; $p = 0.005$). After reviewing the medications and categorising them into analgesics/antipyretics (paracetamol, non-steroidal anti-inflammatory drugs and opioids), gastrointestinal (anti-emetics, anti-spasmodic and antacids), antibiotics, respiratory (beta-agonists, ipratropium bromide and steroids) and others (lidocaine injections and vaccines), neither category was found to be a predictor of cases or controls.

The step-wise logistic regression analysis (Table 3) which included all statistically significant variables, showcases the variables that remained significant. Cases had higher adjusted odds of being hospitalised in the past 30 days prior to the index visit as compared with controls (AOR 19.53, 95% CI 2.45 to 155.44); were more likely to be diagnosed with digestive system disorders (AOR 1.96, 95% CI 1.04 to 3.72); and were more likely to have a high temperature as well as laboratory tests drawn (AOR 2.63, 95% CI 1.26 to 5.48; AOR 3.74, 95% CI 2.15 to

Table 2. Index visit patient clinical characteristics and ED management.

	Cases N = 139 n (%)	Controls N=139 n (%)	p-value
Acuity			
High	5 (3.60)	3 (2.16)	0.005
Medium	127 (91.37)	113 (81.29)	
Low	7 (5.04)	23 (16.55)	
Vital signs			
SBP (low)	6 (5.56)[a]	3 (2.16)	0.185
Heart rate (high)	112 (81.16)[b]	94 (67.63)	0.010
O_2 saturation, ≤95%	10 (7.3)	6 (4.32)	0.289
Temperature, ≥38.5°C	37 (26.62)	16 (11.51)	0.001
Respiratory rate, (high)	51 (46.36)[c]	45 (32.37)	0.024
ED management			
Imaging	31 (22.3)	32 (23.02)	0.886
Laboratory tests (at least one)	96 (69.06)	51 (36.69)	<0.0005
Medications (at least one)	35 (25.18)	57 (41.01)	0.005
Analgesics/antipyretics	18 (12.9)	29 (20.9)	0.08
Gastrointestinal medications	19 (13.7)	16 (11.5)	0.59
Antibiotics	9 (6.5)	3 (2.2)	0.08
Respiratory medications	5 (3.6)	10 (7.2)	0.18
Other	3 (2.2)	9 (6.5)	0.08
IV fluid	21 (15.11)	24 (17.27)	0.625
ECG	2 (1.44)	7 (5.04)	0.173
ED consult	30 (21.58)	25 (17.99)	0.452
Major diagnostic category			
Digestive system	41 (29.50)	27 (19.42)	0.001
Infectious and parasitic diseases	38 (27.34)	24 (17.27)	
Respiratory system	21 (15.11)	16 (11.51)	
Others	39 (28.06)	72 (51.80)	

ED = Emergency Department; SBP = Systolic blood pressure; IV = Intravenous; ECG = Electrocardiogram.
[a]31 missing, [b]1 missing, [c]29 missing.

Table 3. Stepwise multivariate logistic regression of predictors of HRURV.

Variable	AOR (95% CI)	p-value
Hospitalisation (past 30 days)	19.53 (2.45 to 155.44)	0.005
Digestive system	1.96 (1.04 to 3.72)	0.04
Temperature (≥38.5°C)	2.63 (1.26 to 5.48)	0.01
Laboratory tests (at least one)	3.74 (2.15 to 6.48)	<0.0005
Medications given (at least one)	0.35 (0.19 to 0.63)	<0.0005

Variables entered were: hospitalisation [reference (ref) no hospitalisation in the past 30 days], the following discharge diagnosis: digestive and respiratory systems, infectious and parasitic, respiratory system (ref for all diagnoses was other); temperature (ref was <38.5°C); laboratory (ref none done); medications (ref none received); LOS (continuous variable); heart rate (ref was normal); respiratory rate (ref was normal); acuity (ref was low)

6.48 respectively). However, receiving medications during the index ED visit remained a negative predictor of HRURVs (AOR 0.35, 95% CI 0.19 to 0.63).

Discussion

The aim of our study was to determine the incidence and predictors of HRURVs of pediatric ED patients. We found that HRURVs were not common in children, yet several still resulted in ICU admissions or surgical interventions. In addition, our data showed the following variables were significant predictors of HRURV: hospitalisation in the past 30 days prior to the index visit, an initial ED discharge diagnoses of digestive system disorders, a temperature greater than 38.5°C in triage and ED

laboratory tests drawn. On the other hand, administering medications at the index visit was found to be protective for HRURVs.

Several groups have looked at predictors of URVs and HRURVs in children [16,17], however, few looked in-depth at clinical predictors such as vitals on presentation, medication administration and laboratory testing, as we have attempted to do. While prior studies on pediatric HRURVs were retrospective cohort in design comparing URVs to HRUVs, our study is the only case-control that looked at HRURVs alongside a control group that did not revisit the ED within 72 hours, allowing for a more robust exploration of predictors. HRURVs highlight a specifically high-risk ED group that requires admission on the return visit, some of which included ICU stays and surgical interventions. Understanding predictors of this group is important to focus efforts on reducing this morbidity. Because of the matching process, age could not be assessed as a predictor. However, age has already been studied extensively as a predictor of URVs and HRURVs in multiple studies, with some studies reporting younger age as a predictor of URVs and others pointing to an older group (greater than 12 years old) being at risk [13,17].

Our overall incidence of URVs was 5.35% and that of HRURVs was 0.96% with an admission rate of 17.9%. These numbers fall within the range found in the literature with pediatric URV rates between 3% and 7% and admission rates between 11% and 19% [13,16]. They are, however, slightly higher than those reported for adults;

while mortality, ICU and surgical intervention rates are lower [18]. This may be because of re-visits related to increased parental anxiety with the progression of the disease rather than an issue with medical-decision making at the index visit. Interventions targeting the effectiveness of discharge instructions, which have been shown to decrease URVs, may address this issue especially if coupled with follow-up phone calls or scheduled follow-up visits with the primary care provider [19].

The complexity of the index visit case has been found to be predictive of URVs in other studies. Measures of complexity that have been reported include acuity and LOS [12,20]. While these two metrics fell out at the multivariate analysis in our study, recent hospitalisation and ED laboratory testing remained as significant predictors. The latter two are probably markers of complexity with which level of acuity and LOS were co-linear. In fact, acuity, as measured by ESI, is partially based on expected resource requirements, including laboratory testing and diagnostics required within the ED visit, all of which drive ED LOS. Recent hospitalisation was found to be strongly predictive and may reflect a subset of patients with chronic conditions or comorbidities that place them at higher risk for return visits. Prior studies on HRURVs in pediatrics have also found recent hospitalisation to be predictive of HRURVs, however, these only considered hospitalisation within 7 days, whereas our data suggests that the effect remains even with hospitalisations as far back as 30 days [13].

While the expected need for parenteral medication requirement is also factored into ESI scoring and reflects complexity of the case, receiving medications were found to be protective of HRURV in our study. To our knowledge, this has not been explored as a unique variable in URVs or HRURVs. This could reflect issues related to the physician's clinical judgement in deciding on medications required during the ED visit or could be related to specific medications that may reduce the risk of disease progression or return visits. Studies that have looked at medication usage in specific disease entities have shown mixed results in terms of impact on HRURVs. For example, giving anti-emetics in the ED for acute gastroenteritis did not decrease bounce-back rates [21]; yet, giving an antibiotic in the ED for community-acquired pneumonia did [22]. None of our categories of medications was found to be significant. However, our study was not powered to look at this specifically. This is an area that warrants further exploration with larger studies.

The two main predictors of HRURVs related to the clinical presentation at index visit were fever at triage and discharge diagnosis of digestive system disorder. While abnormal vital signs at ED discharge have been associated with increased ED return visits [23], fever at triage has not been previously reported as a predictor. Given the complexity of decision making around fever in pediatrics, especially in those less than 36 months, and the plethora of studies that attempt to streamline evidence-based approach to this complaint, it is not unexpected for it to emerge as a risk factor for HRURVs. Diagnosis of digestive system disorders was also found to be predictive of HRURVs, in line with other prior

studies. The symptoms of abdominal pain, vomiting or diarrhoea have a wide differential from benign diagnoses such as constipation, to acute gastroenteritis or surgical emergencies such as appendicitis. In fact, appendicitis still has high rates of misdiagnoses (4%-6%), especially when children present with vague gastrointestinal complaints [24,25]. Developing protocols for these two high-risk groups, those presenting with fever and those discharged with digestive system disorders, that include pre-discharge assessments or targeted telephonic follow-up can be ways to reduce HRURVs in these patients.

Interestingly, visit related factors such as daily ED volume (often used as a reflection of ED crowdedness) time of ED visit and handover were not found to be risk factors for HRURVs in our sample. Several pediatric URV papers have found off-hours visits (nights and weekends) to be predictors of return visits, including HRURVs [17,20]. Our data did not support this nor does a literature review of URVs by Tran et al, [26]. Although handover was reported to be a risk factor for HRURVs in a prior study on adults in the same setting [18], this was not the case in our study. It is of note though that the number of HRURVs who had a handover during their initial ED visit was low (28 compared to 17 for controls) with a *p*-value trending towards the significance at 0.05. Since handover has been shown to increase adverse events in the ED, more studies looking at this in children are needed. It is possible that visit related factors, specifically volume and time of ED visit, were not a risk factor in our population as our staffing model has high provider to patient ratios, even on off hours, to meet our community's expectation of minimal wait time.

Finally, these results highlight the need to develop systematic, targeted protocols addressing the predictors of HRURVs in pediatrics. Such interventions have been shown to be effective in decreasing rates of pediatric URVs, although not necessarily HRURVs [19]. The study findings can also be used to explore deriving clinical prediction rules to anticipate at-risk patients who need targeted interventions or require admission at the index visit.

Limitations

Our study has some potential limitations. The case-control design relied on a retrospective chart review and therefore includes only information available in the chart and cannot provide explanations of causation. Matching controls to age limited our ability to explore age as a predictor, however it allowed for the exploration of clinical variables, including diagnosis, for which practical targeted interventions can be explored. Our single center design could affect the external validity of our findings, although AUBMC is the largest medical center in Lebanon and receives patients from all over the country. While patients who initially visited other EDs and then presented to our institution might have been mislabelled as controls, we believe this number to be negligible since most patients tend to seek care at the same institution and the majority of our ED patients are not new to our system. Finally, patients who revisited

other EDs would not have been captured in our study. We believe, however, this number to be negligible since our ED is the busiest and largest in the area.

Conclusion

In summary, we identified several new predictors of HRURVs including hospitalisation in the past 30 days, laboratory testing, fever, a digestive system diagnosis. Further research to evaluate these predictors in different settings is important while we focus on interventions targeting patients who present with these high-risk features at our institution. Receiving medications in the ED seems to be protective and requires further research to identify specific medication categories that may be driving this finding.

List of Abbreviations

AOR   Adjusted odds ratio
AUBMC   American University of Beirut Medical Center
CI   Confidence interval
ED   Emergency Department
EM   Emergency Medicine
ESI   Emergency Severity Index
HRURV   High risk unscheduled return visit
ICU   Intensive care unit
LOS   Length of stay
SBP   Systolic blood pressure
SD   Standard deviation
URV   Unscheduled return visit

Conflict of interest
None to be declared.

Ethical approval
This study was approved by the Institutional Review Board (IRB) of the American University of Beirut with IRB ID ED.EH.05, dated 5 November, 2015.

Author contribution
EAH, ZO, RS and HT conceived and designed the study. EAH coordinated the study throughout. EAH had full access to all of the data in the study and takes responsibility for the integrity of the data. SA helped with proposal drafting and data extraction. HT and RK analysed and interpreted the data. EAH, SA and RS drafted the manuscript. All authors critically revised the manuscript and approved the final version. The lead author, EAH, affirms that this manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Data sharing
Data are available on reasonable request.

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