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Appropriate Use of Antibiotics among Pediatric In-Patients: An Interventional Randomized Controlled Study

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Abstract

Background and Aims: Pediatric patients are considered a special patient population for medication use. The study aims to assess the role of clinical pharmacists in the appropriate use of antibiotics among inpatient pediatrics and to evaluate some infection-related outcomes.

Method: The study was designed as an interventional randomized controlled trial, where 132 patients from the internal pediatric ward in a main hospital in Jordan were included. Pediatric patients were divided into three age groups. Each age group was sub-grouped into control and intervention groups. All patients` caregivers were interviewed, and patients' medical files were reviewed. All antibiotic-related problems and their side effects were documented. Recommendations to solve these problems were made to the treating physician or administering nurse in the intervention group. Follow-up data were collected for each group.

Results: After a review of cases, the most frequent antibiotics-related problems found were administration errors. The antibiotic-related problems were reduced in the intervention group by 70.67% with a high response rate from the medical team. The mean length of stay in the control group and implemented intervention group was 8.02 days and 6.7 days respectively, with a significant difference (p=0.039). The incidence of side effects associated with the inappropriate use of antibiotics was also reduced.

Conclusions: The clinical pharmacist interventions in our study resulted in enhancing the appropriate use of antibiotics among inpatients pediatrics and decreasing the mean length of stay as well as the incidence of side effects associated with the inappropriate use of antibiotics.

Keywords: Antibiotics, pediatric, in-patients, dose, errors.

INTRODUCTION

Antimicrobial agent is a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kills or inhibits the growth of microorganisms) at concentrations attainable in vivo. This group of medications needs to be selected and administered appropriately to ensure appropriate use [1], as it is considered one of the most widely used groups of medications in the world [2]. The selection of specific antibiotic is dependent on the diagnoses, the most probable causative organism at the site of infection, the place where the infection was acquired, the age of the patient, host factors (i.e. corticosteroids use, cancer therapy or transplant), and mechanical factors (i.e. use of a ventilator or urinary catheter). Sometimes it is difficult to identify the causative agent, in these cases specimens are needed, as well as laboratory testing, for identification [3]. The most commonly used agents of the antimicrobial group are antibacterial agents [1].

Pediatric patients are considered to be a special patient population [4]. There are different considerations regarding drug pharmacodynamics and pharmacokinetics [5]. These different considerations and the excessive use of antibiotics make pediatrics an important population to study the dosage regimen of antibiotics [4].

According to a prospective cohort study done in eight countries between 2009 and 2014, there is a common repeated exposure to antibiotics in children in the first two years of life with the incidence of 4.9 courses per each child per year [6]. In a retrospective cross-sectional study done in Ethiopia, 64.42% of total prescribed medications for pediatrics in the study were antibiotics with a an average of 1.09 antibiotics per patient [7].

The misuse of antibiotic medications leads to an increase in antibiotic resistance [8] and the clinical pharmacist has an important role in controlling antibiotic resistance by ensuring the appropriate use. The European Society of Clinical Pharmacy defined clinical pharmacy in 2010 as a 'health specialty, which describes the activities and services of the clinical pharmacist to develop and promote the rational and appropriate use of medicinal products and devices'. This definition explains the important role of the clinical pharmacist in the appropriate use of medication due to the presence of inappropriate medication prescriptions. This is especially true with regard to antibiotics [9]. Nowadays clinical pharmacists are part of the medical team of several hospitals in the USA because of their important role in shortening the length of stay (LOS) in hospitals, decreasing the incidence of side effects, and decreasing mortality [10].

AIM OF THE STUDY

The aim of this study was to assess the role of the clinical pharmacist in the appropriate use of antibiotics in pediatrics (prescribing and administration) and to evaluate outcomes related to length of stay and medication-related side effects.

METHODS

Ethical approval

The study was approved by the Scientific Committee at the School of Pharmacy/The University of Jordan and the School of Postgraduate Studies at the University of Jordan. Ethical approval from the Ministry of Health and Al-Bashir Hospital was obtained. In addition, guardians of patients who met the inclusion criteria of the study were invited to enroll their children in the study and sign the informed consent form.

Study design

This study was designed as an interventional randomized controlled trial. It was carried out at the internal pediatric ward in Al-Bashir Hospital in Jordan over five months in 2018. Inclusion criteria were patients aged from birth to younger than 13 years old, whose parent or guardian consented to enrollment and treated with antibiotics in the internal pediatric ward in Al Bashir Hospital. Patients who were enrolled in the study and readmitted to the hospital during the study period were not enrolled again. During the enrolment period, patients who met the inclusion criteria were grouped according to age into three age groups. In each group, patients were randomly distributed (using www.randomization.com) into the control group and intervention group (the sample size was equal to 66 for each of the control and intervention groups).

Randomization

Patients who met the inclusion criteria, were distributed into 3 groups according to age:

A- From birth to younger than 3 months (group A).

B- From 3 months to younger than 3 years (group B).

C- From 3 years to younger than 13 years (group C).

Within each group, patients were randomly distributed to control or intervention group using the web site www.randomization.com as a blocked design randomization according to age groups (A, B and C).

Data Collection

For patients meeting the enrolment criteria medication charts and computerized patient files in the internal pediatric ward for inpatients who were admitted to Al-Bashir Hospital were reviewed by the researcher pharmacist, the patients` caregivers were interviewed and missing information was obtained. During enrolment, patient cases were reviewed three days weekly; on each day the first six to ten patients who met the study criteria were invited to be enrolled. For each patient in both control and intervention groups antibiotics were reviewed according to the antibiotic guidelines (Infectious Disease Society of America (IDSA) and or American Academy of Pediatrics (AAP)), Trissle`s IV Chek, medication leaflet, Neofax, Lexicomp, and The Harriet Lane HnadBook 21st edition. Any observed medical error related to antibiotics was classified according to Drug Related Problems classification by AbuRuz et al (2006) [11]. In the control group, patients were noted without any interventions. They received normal care from other members of the medical team. In the intervention group, the patient's status was noted, and the errors were recorded and discussed with the physician. The suggested interventions were written in a consult note, discussed, signed by the treating physician or administering nurse (either agreed or disagreed), and recorded. Both groups were followed up during and after hospitalization (Parents were contacted by telephone for follow-up). Follow-up data were noted according to the type of error which included the observation of vital signs, relief of infections, adverse effects, culture results, and lab tests.

Statistical Analysis

Analysis was performed through version 22 of SPSS software. The Chi-square and Fisher`s Exact Tests were used in calculating the P value for categorical data. Shapiro-Wilk Test for normality was used for numerical data, for non-normally distributed data Mann-Whitney U test was used, P value significance level was considered at < 0.05.

RESULTS

Demographical Results

Over three months, there were 1058 admissions to the internal pediatric ward in Al-Bashir Hospital. We interviewed 133 (12.57%) guardians/caregivers of patients who received antibiotics and met the inclusion criteria. Out of the 133 interviewed guardians/caregivers, 132 (99.25%) agreed to participate in the study as illustrated in Figure (1).

The one hundred thirty-two patients were divided with regard to gender and males accounted for 50.76 %, (67) patients. However, the age groups had a significant difference in the gender ratio between the three age groups (P value < 0.0005). The majority of Group A were males (72.73%), the opposite was the case in Group C (72.73% of the patients were females), and in Group B 52.28% of the patients were males. There was no significant difference in the gender ratio between the control group and the intervention group (P value = 0.728).

Antibiotics Prescription

There were 174 antibiotics prescribed for the 132 patients in the study, with an average of 1.32 antibiotics prescriptions per patient. The higher prescription percentage was for ceftriaxone (59.2%), vancomycin (9.2%), and amikacin (8.62%). Within the three age groups, the most frequently prescribed antibiotic was ceftriaxone with different percentages among the three groups (Table 1); while the second more frequent antibiotic was different within the three groups. These differences were predictable due to the difference in percentages of diagnoses.

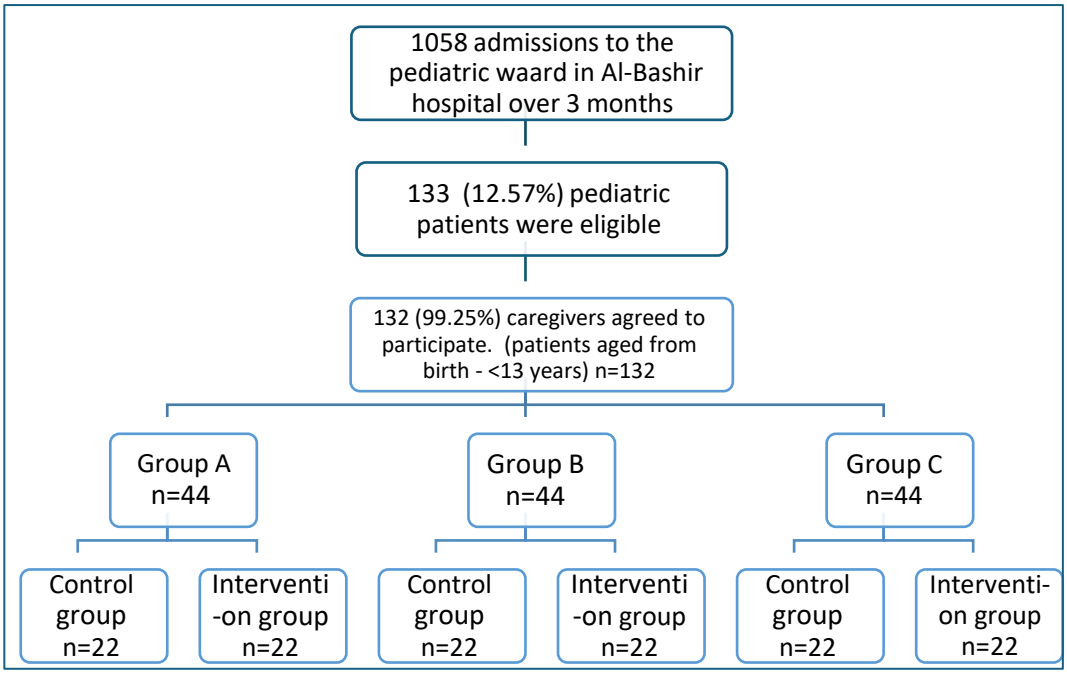

Figure 1. Samples Distribution.

n; sample size.

* From birth to younger than 3 months (group A).

† From 3 months to younger than 3 years (group B).‡

From 3 years to younger than 13 years (group C).

Table 1. Frequency and Percentage of Prescribed Antibiotics between Patients` Age Groups

Antibiotic	Route	Group A		Group B		Group C		Total Groups	
		f	%	f	%	f	%	f	%
Ampicillin	IV	7	12.50	0	0.00	1	1.59	8	4.6
Ceftriaxone	IV	36	64.29	36	65.45	31	49.2	103	59.2
Cefotaxime	IV	6	10.71	1	1.82	2	3.17	9	5.17
Cefuroxime	IV	0	0.00	1	1.82	1	1.59	2	1.15
Imipenem \Cilastatin	IV	0	0.00	1	1.82	1	1.59	2	1.15
Amikacin	IV	1	1.79	5	9.09	9	14.29	15	8.62
Gentamycin	IV	2	3.57	0	0.00	2	3.17	4	2.30
Vancomycin	IV	3	5.36	6	10.91	7	11.11	16	9.20
Azithromycin	Oral	1	1.79	2	3.64	3	4.76	6	3.45
Clarithromycin	Oral	0	0.00	0	0.00	1	1.59	1	0.57
Metronidazole	IV	0	0.00	2	3.64	3	4.76	5	2.87
Metronidazole	Oral	0	0.00	1	1.82	0	0.00	1	0.57
Rifampicin	Oral	0	0.00	0	0.00	1	1.59	1	0.57
Doxycycline	Oral	0	0.00	0	0.00	1	1.59	1	0.57
Total		56	100.01	55	100.01	63	100.00	174	99.99

IV, intravenous; f, frequency; %, percent.

* From birth to younger than 3 months (group A).

† From 3 months to younger than 3 years (group B).

‡ From 3 years to younger than 13 years (group C).

Antibiotics-Related Problems Analysis

Reviewing the cases of 132 patients, 166 Antibiotics Related Problems *(*ARPs) were reported. The most frequently reported ARPs were administration errors (62.05%), followed by a need for additional or more frequent monitoring (18.67%), then dosage regimen errors, and the need for stepping up (7.23% for each). Table (2) illustrates the percentage for each one of the ARPs, and the difference between them in the control and intervention group. In all three age groups the most frequent ARPs were administration errors with different percentages, see Table 3 for details.

Table 2: Antibiotics Related Problems` Percentage between Control and Intervention Groups

Antibiotic related problem categories	Control Group		Intervention Group		Total	
	f	%	f	%	f	%
1-More effective drug is available/recommended	0	0.00	2	2.67	2	1.20
2- The patient requires stepping up.	9	9.89	3	4.00	12	7.23
3- Efficacy dosage regimen issue	5	5.49	7	9.33	12	7.23
4-The current antibiotic is contraindicated/unsafe for patient condition and should be stopped, monitored, or replaced.	2	2.20	1	1.33	3	1.81
5- Safety dosage regimen issue	2	2.20	1	1.33	3	1.81
6-Adminstration error	58	63.74	45	60.00	103	62.05
7- A need for additional or more frequent monitoring.	15	16.48	16	21.33	31	18.67
Total	91	100.00	75	99.99	166	100.00

F, frequency; %, percent.

Table 3. Antibiotics Related Problems` Percentage between the Different Age Groups.

Antibiotic related problems	Group A		Group B		Group C	
	f	%	f	%	f	%
1-more effective drug is available/recommended	2	3.70	0	0.00	0	0.00
2- The patient requires stepping up.	1	1.85	3	5.88	8	13.11
3- Efficacy dosage regimen issue	6	11.11	1	1.96	5	8.20
4-The current antibiotic is contraindicated/unsafe for patient condition and should be stopped, monitored, or replaced.	2	3.70	0	0.00	1	1.64
5- Safety dosage regimen issue	2	3.70	1	1.96	0	0.00
6-Adminstration error	37	68.52	36	70.59	30	49.18
7- A need for additional or more frequent monitoring.	4	7.41	10	19.61	17	27.87
Total	54	99.99	51	100.00	61	100.00

F, frequency; %,percent.

* From birth to younger than 3 months (group A).

† From 3 months to younger than 3 years (group B).

‡ From 3 years to younger than 13 years (group C).

Out of 132 patients, 108 (81.82%) patients had one ARP in antibiotic, 16 (12.12%) patients had two ARPs, and 8 (6.06%) patients had more than two ARPs. To compare the control group and intervention group, in the control group, 75.76% of patients had one ARP, 13.64% had two ARPs and 10.61% had more than two ARPs while in the intervention group, the percent was 87.88%, 10.61%, and 1.52% respectively with no significant difference in number of errors/patient (P value = 0.069) between the two groups. Ceftriaxone followed by amikacin, vancomycin, and ampicillin, respectively, were the most frequently recorded antibiotics with medication errors within the 174 antibiotics prescribed for all patients in the study.

Pharmacist Intervention

From 75 ARPs in the intervention group, 53 (70.67%) interventions were agreed. In 6 (8%) ARP interventions, the treating medical team disagreed with recommendations, and 16 (21.33%) interventions were agreed but not implemented (errors that need more monitoring) because the hospital lacks the needed test for monitoring.

To compare pharmacist interventions for different ARPs between different age groups, the percent of ARPs corrected in each group were 73.08%, 66.67%, and 75% for groups A, B, and C, respectively, with differences in the type of ARPs corrected in each group. The percent of correction achievement in group A was 100% for the following: the current antibiotic was contraindicated/unsafe for the patient's condition and should be stopped, monitored, or replaced, safety dosage regimen issues and administration error, 50% for more effective drug was available/recommended, while ARPS for efficacy dosage regimen issue was not/span>corrected. In group B the percent of correction achievement was100% for the administration error while it was 0% for patients required stepping up. In group C the percentage of correction achievement was 100% for efficacy dosage regimen issues, the patient required dose stepping up and administration errors. In all three groups APRs related to a need for additional or more frequent monitoring were not implemented due to the lack of the needed test (medicine blood level test).

In the control group the mean LOS was 8.02 (±3.6) days, while in the implemented intervention group it was 6.7 (±2.9), with a significant difference (p value = 0.039) between the two groups. P value was calculated by the Man-Whitney U test because LOS data were not normally distributed.

Outcomes Related to Ceftriaxone Administration

All prescribed ceftriaxone contained an administration error by the administration of ceftriaxone as intravenous push instead of intermittent. Stated reasons given to the clinical pharmacist by the medical team during the study were as follows: high number of patients assigned to each nurse (ranged from 16-20 patients/nurse), lack of dose flow intravenous set that could control timing without the need to be checked throughout the administration and high rate of ceftriaxone prescriptions in the internal pediatrics department.

Side effects reported (at the time of enrolment and before intervention) regarding patients receiving ceftriaxone were burning and vomiting, due to administrating ceftriaxone as one push. In group A 81.08% of patients/caregivers reported burning and 2.7% reported vomiting. In group B, the percentages of burning and vomiting were 94.44% and 2.78%, respectively. In group C the percentages of burning and vomiting were 83.33% and 10%, respectively. No significant difference was noted between age groups in side effects, taking into consideration that there were patients who reported both side effects, while 11.65% of patients/caregivers did not report any side effects in all groups. After intervention, burning was relieved in 87.8% of patients and 100% of vomiting cases stopped vomiting after our intervention**.**

DISCUSSION

Out of 132 patients, 67 (50.76%) patients were males, and 65 (49.24%) were females. No significant difference in gender distribution between the control and intervention groups was noted (P value = 0.728). This agrees with a survey done among children in Madagascar and Senegal that found no difference in pediatric genders between the three areas in the survey for patients younger than two years [12]. Similar distribution was reported in another study that had 51.6% males and 48.4% females in the sample that included pediatrics up to six years old [13]. In another study done among hospitalized pediatric patients from the South Area of the West Bank – Palestine, the sample size included 60.5% males and 39.5% females, which were different from the total male and female percentages in our study. In this study inpatients pediatrics younger than 16 years old in three governmental hospitals were included, while we studied inpatients pediatrics younger than 13 years old in one governmental hospital [14].

In 132 patients in the study who were treated with antibiotics, an average of 1.32 antibiotics were prescribed per patient. In a study done among hospitalized children in tertiary care children's hospital in Tehran, the average number of antibiotics prescribed per patient was 1.82 antibiotics and ceftriaxone was the most frequent antibiotic used [15]. This agreed with our study in which the most frequently prescribed antibiotic in our study was ceftriaxone (59.2%).

Different data were found in a study done in the pediatric emergency department at Georgetown Public Hospital which found that B-lactam penicillins were prescribed most frequently (51.4 %), followed by sulfonamides (13 %), cephalosporins (7.7 %)

and fluoroquinolones (1.7 %). This difference from our results might be due to the differences in the percentages of the managed infections throughout our study and therefore differences in the antibiotic used. In addition, their study was done in the emergency department in South America [16].

The most frequent antibiotics that contained medication errors in our study in descending order were ceftriaxone, amikacin, vancomycin, and ampicillin. While Macrolides, co-trimoxazole then B-lactams had higher medication error rates in the pediatric medical and the pediatric surgery ward in a study done in the University Children's Hospital of Zurich, Switzerland [17]; our study was done in the internal pediatric ward which could explain the difference.

The total number of ARPs in 174 prescribed antibiotics was 166 problems. The most frequently reported ARPs were administration errors (62.05), followed by a need for additional or more frequent monitoring (18.67%), then efficacy dosage regimen errors, and the need for stepping up (7.23% for each). Fewer ARPs reported; the more effective drug is available or recommended (1.2%), safety dosage regimen issue and current antibiotic is contraindicated or unsafe for patient condition and should be stopped, monitored, or replaced (1.81% for each). These findings differ from a study done to assess clinical pharmacy activity in a pediatric inpatient department in Cote d'Ivoire, which used the classification of drug-related problems of the French Society of Clinical Pharmacy. The main drug-related problems in pediatrics were noncompliance with recommendations (24.1%), overdose (21.1%), and underdosing (13.8%). Unlike their study, this study of antibiotics-related problems and not drug-related problems [10]. Another study was done in Palestine (which was done for a higher range of ages), which found that 22.4% of prescribed medication had medication dosing errors [14].

The most frequent ARPs were administration errors in all age groups. A systematic review of medication errors in Middle East countries reported 9.4 % to 80 % administration errors within studies in the Middle East included in the systematic review, in which Jordan was included. The variation in definitions of medical errors, methodologies, and settings within different studies in different countries, may cause the variation between studies in the rate of error reported [18].

Of the 166 reported ARPs, 75 ARPs were in the intervention group. Medical team acceptance of our intervention was 70.67% with a significant difference between total ARPs in the intervention group and the implemented ARPs (P value = 0.001). This result agreed with the study done in the Pediatric Inpatient Department in Cote D'ivoire which reported an acceptance rate of 67.3% while assessing the role of clinical pharmacists in pediatric inpatients [10]. The highest percent of correction achievement was for administration errors, antibiotics that were contraindicated or unsafe for patient condition, and safety dosage regimen issues with a correction percent of 100% for each. This agreed with the study done in the Pediatric Inpatient Department in Cote d'Ivoire that found dose adjustment (31.8%), and accuracy of drug administration (29.3%) were the most important pharmacist interventions [10]. Moreover, the pharmacist intervention resulted in decreased LOS. These results agree with reported results from a randomized controlled trial done in West China Second University Hospital, which reported a significant difference in the mean

LOS. The mean LOS in the control group was 9.06 days, while it was 7.33 days in the intervention group [19].

We reported the readmissions of the patients in the study within one month after regular discharge from the hospital. There was no significant difference between a number of readmissions in control and intervention groups. This result agreed with the randomized controlled trial done in West China Second University Hospital that found no significant difference in readmission between the control group and intervention group [19] .

Strengths of the research

This is the first interventional study in Jordan, done to study the role of clinical pharmacist in the appropriate use of antibiotics in the pediatric ward. The study was approved by the Scientific Committee at the School of Pharmacy/The University of Jordan and the School of Postgraduate Studies at the University of Jordan. An ethical approval from the Ministry of Health and Al-Bashir Hospital was obtained.

Limitations

Since our study was performed in a single center, the results may not apply to other settings. The severity of the detected antibiotics-related problems was not determined and the researcher was not present in the pediatric wards at all times. This might reduce the clinical pharmacist's effect on patient outcomes.

CONCLUSION

In conclusion, our study demonstrates that pharmacist intervention in pediatric wards enhanced the appropriate use of antibiotics, decreased the length of stay, decreased side effects of inappropriate antibiotics administration, and increased medical team awareness toward side effects related to inappropriate administration of ceftriaxone. Clinical Pharmacist interventions were accepted at a high rate by healthcare providers.

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Declaration of Conflicting Interests

The author(s) declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Impact of findings on practice

- The most frequent antibiotics related problems were related to administration errors.
- The antibiotic related problems as well as antibiotics related side effects were significantly reduced in the intervention group
- The mean length of stay was significantly less in intervention group.

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الاستخدام الملائم للمضادات الحيوية في الأطفال المرضى المنومين في المستشفى: دراسة تداخلية

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الملخص

الخلفية و الأهداف: يعتبر الأطفال من مجموعات المرضى الخاصة؛ حيث لديهم اعتبارات خاصة فيما يتعلق باستخدام الأدوية. تهدف دراستنا الى تقييم دور الصيدلاني السريري في الاستخدام الملائم للمضادات الحيوية للأطفال المنومين في المستشفى .

المنهجية: تم تصميم الدراسة كدراسة عشوائية مضبوطة. حيث تم توزيع 132 مريض من قسم الأطفال الى 3 مجموعات عمرية، و تم اعادة توزيع كل مجموعة الى مجموعة ضابطة و مجموعة تدخل. ثم تم مقابلة جميع اهالي الاطفال المرضى، و مراجعة ملفاتهم الطبية، و تسجيل جميع الاخطاء المتعلقة بالمضادات الحيوية و آثارها الجانبية. في مجموعة التدخل تم تقديم التوصيات الى الاطباء المعالجين و الممرضين لمعالجة هذه الأخطاء و تسجيل بيانات المتابعة لكل المجموعات.

النتائج: كان أكثر نوع خطأ متعلق بالمضادات الحيوية هو الخطأ المتعلق بالحقن. حصلنا على نسبة تصحيح للأخطاء في مجموعة التدخل مقدارها 70.67 % و معدل استجابة عالية من قبل الفريق الطبي مع وجود فرق معنوي بنسبة الاخطاء قبل و بعد التدخل. معدل البقاء في المستشفى للمجموعة الضابطة و مجموعة التدخل كان 8,02 و 6,7 يوم على التوالي مع وجود فرق معنوي. مع تسجيل انخفاض في معدل الآثار الجانبية المتعلقة بعدم الاستخدام الملائم للمضلدات الحيوية في مجموعة التدخل.

الاستنتاجات: أظهرت الدراسة أن وجود الصيدلاني السريري يعزز الاستخدام الملائم للمضادات الحيوية لدى الأطفال المنومين في المستشفى، و يقلل معدل البقاء في المستشفى كما يقلل نسبة حدوث الآثار الجانبية المصاحبة لعدم الاستخدام الملائم للمضادات الحيوية.

الكلمات الدالة: المضادات الحيوية, الأطفال, المنومين في المستشفى, جرعة, الأخطاء.