International Journal of Pharmacy and Pharmaceutical Sciences

ISSN- 0975-1491 Vol 8, Issue 1, 2016

Original Article

A STUDY OF CLINICAL PHARMACIST INITIATED INTERVENTION FOR THE OPTIMAL USE OF MEDICATIONS IN A NEONATAL INTENSIVE CARE UNIT (NICU) OF A TERTIARY CARE HOSPITAL, SOUTH INDIA

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Received: 29 Nov 2014 Revised and Accepted: 18 Nov 2015

ABSTRACT

Objective: Various strategies to reduce errors have been described in adult and pediatric patients, but there are few published data on their effect in the NICU. The study was carried out to assess the impact of a clinical pharmacist-initiated intervention for the optimal use of medications in NICU.

Methods: A prospective, non-experimental, Interventional study was conducted, with a sample size of 150 patients, admitted to the NICU during a period of 7 mo.

Results: A total of 87 Drug-related problems (DRPs) were identified from 80 patient case records. Most of the pharmacist-initiated interventions carried out in this study resulted from Dose/frequency inappropriate (40.22%) followed by Administration errors (31.05%) and Drug Interactions (17.24%). The acceptance rate of recommendation and change in drug therapy was found to be high 68.97%. Most of the pharmacist interventions were seen to have moderate significance in grade.

Conclusion: This study demonstrates that the physician's acceptance rate of pharmacist intervention is high. The physician acceptance rate of documented clinical pharmacist interventions indicated that specialist medical colleagues considered most of the interventions appropriate. This suggests that a joint effort between physicians and pharmacist is possible that provides a safer system, improved pharmaceutical care and better resource utilization.

Keywords: Clinical pharmacist, Interventions, Drug-related problems.

INTRODUCTION

The neonatal period is a highly vulnerable time for an infant who is completing many of the physiologic adjustments required for extra-uterine existence [1]. Because of the vulnerable nature of the NICU patients, the complexity of the medications used and challenges of the NICU environment, preparing and administering medications to neonatal patients are inherently risky. Patients in the NICU are undergoing maturational changes in drug sensitive areas such as the renal and hepatic systems and thus may have variable responses to drugs. Medications are universally weight -based, requiring calculations for each dose. NICU patients often have long hospital stays, increasing their exposure to medications and medication errors. NICU patients are nonverbal and unable to participate actively in the patient identification process, which increases the likelihood of wrong patient errors [2].

Medications commonly used in the NICU are an independent risk factor for medication errors. Often the medications dispensed are adult-strength, requiring complex, multistep dilutions prior to dispensing or administering them, which increases the opportunity for errors. Clinical pharmacists have a central role in drug safety by contributing to the prevention, identification, documentation, and reporting of Adverse Drug Reactions (ADRs) Clinical pharmacy services helps in monitoring drug therapy in this area, thereby getting benefits for the patients.

MATERIALS AND METHODS

Settings

The study was carried out at the NICU of Amrita Institute of Medical Sciences (AIMS), Kochi which is a 1200 bedded tertiary care teaching hospital.

Study design

It was a prospective, non-experimental and Interventional study

Duration of study

The study was designed for a period of 1 y in which data collection was done for a period of 7 mo from 1st September 2011 to 31st March 2012.

Study population

The present study was conducted on 150 patients who were admitted into the NICU during a period of 7 mo. All the patients having age≤ 2 8 d at the time of admission to the NICU and those who are on medications were included in the study. Whereas patients are having age>28 d at the time of admission to the NICU and those who are not on medications were excluded.

Data source

Patient's data relevant to the study like demographic data, current medication, laboratory investigation, past medical and medication history were collected from the patient's progress records, treatment charts, laboratory reports and patient's history records and recorded in the standardized data collection form.

Methodology

Clinical pharmacist routinely monitored patient's drug therapy and intervened with physicians as well as nurses when necessary. The identified medication-related problems were discussed during ward rounds with the concerned physicians and documented in the standardized intervention form. The acceptance level of physician for the particular intervention was also recorded as either accepted or not accepted. In addition, the total time taken by the intervening pharmacist in preparing and undertaking the intervention was recorded. All the interventions made by the intervening pharmacist were preceded by consultation with the academic clinical pharmacist. The academic, clinical pharmacist assessed the clinical significance of each intervention.

RESULTS AND DISCUSSION

Results

A total of 150 patients admitted into the NICU during the study period were included in the study.

Out of which 80 patients had drug related problems in which 52 were males and 28 were females. Out of 80 patients, 87 drug related problems were identified and assessed. The mean gestational age at birth was 35.55±3.467 w (range = 24–40 w). The mean birth weight of the study population is summarized in table 1.

Table 1: Mean birth weight of the study population

Gender	Male	Female	Total
Number	86	64	150
Mean	2.455	2.129	2.316
Median	2.54	2.30	2.40
SD	0.871	0.847	0.873
Range	0.7-4.4	0.6-3.7	0.6-4.4

Most of the pharmacist-initiated interventions carried out in this study resulted from Dose/frequency inappropriate (40.22%) followed by Administration errors (31.05%) and Drug Interactions (17.24%). The pharmacist-initiated interventions during the study period are summarized in fig. 1.

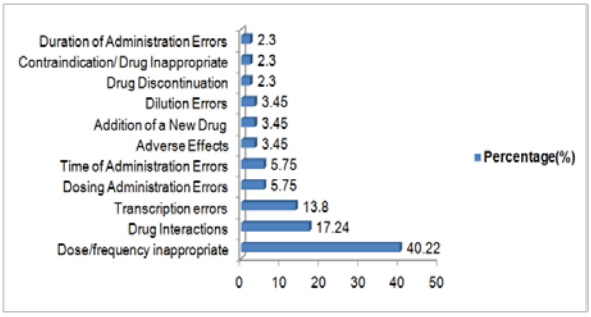

Fig. 1: Intervention types of all patients

The test of proportions was used to evaluate the interventions between In-born and Out-born patients (table 2), Patients admitted with or without additional surgical care (table 3) and Preterm-Term patients (table 4).

Table 2: Evaluation of intervention carried out in In-born and out-born patients

In-born/ out-born	Number of patients	Number of interventions	Proportion
In-born	71	26	0.366
Out-born	79	61	0.772
Total	150	87	0.580

Z =-5.030 & p<0.001

Here a low p–value indicates that the proportion between in-born and out-born population is significant at 0.1%. Further, a high proportion of 0.772 shows that the out-born babies need more number of interventions.

Table 3: Evaluation of intervention carried out in patients with/without additional surgical care

Patients	Number of patients	Number of interventions	proportion
With Surgical Care	31	21	0.677
Without surgical Care	119	66	0.555
Total	150	87	0.580

Z = 1.521 & p = 0.128

Here p–value is greater than the significance value 0.05, we conclude that the proportion between two groups of populations is not significant at 5%.

Table 4: Evaluation of intervention carried out in preterm and term patients

Gestational age	Number of patients	Number of interventions	Proportion
Pre-term	74	38	0.514
Term	76	49	0.645
Total	150	87	0.580

Z =-1.626 & p = 0.104

Here p–value is greater than the significance value 0.05, we conclude that the proportion between two groups of populations is not significant at the 5 % level of significance.

Table 5 illustrates that out of 87 interventions, 60 (68.97%) of the recommendations were accepted, and therapy was changed. 18 (20.69%) of the interventions were accepted, but therapy was not changed. Only 9 (10.34%) of the interventions were neither accepted, nor therapy changed. The physician acceptance rate was found to be high.

Table 5: Results of clinical pharmacist recommendations

Recommendations	Number of recommendations	Percentage (%)
Suggestion accepted, and therapy changed	60	68.97
Suggestion accepted, but therapy not changed	18	20.69
Neither suggestion accepted nor therapy changed	9	10.34
Total	87	100

Out of 87 interventions, the significance grades of interventions were found to be 'Moderate' (55.17%), 'Minor' (33.33%) and 'Major' (11.49%). The representation of the significance grade of interventions is represented in fig. 2.

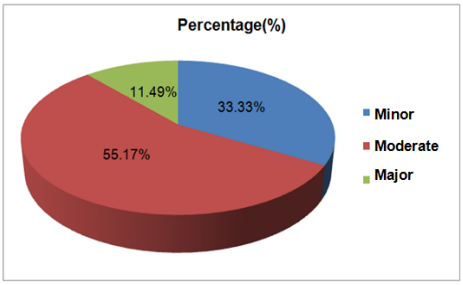

Fig. 2: Representation of the percentage of the grade of Interventions

***Minor**

Problems requiring small adjustments and optimization to therapy, which are not expected to alter significantly hospital stay, resource utilization or clinical outcome.

Moderate

Problems requiring adjustments, which are expected to enhance the effectiveness of drug therapy producing minor reductions in patient morbidity or treatment costs.

Major

Problems requiring intervention, expected to prevent or address very serious drug-related problems, with a minimum estimated effect on reducing hospital stay by not less than 24 h.

The time taken for the intervention by the clinical pharmacist were found to be 15 min or less in 34 (39.08%), 15-30 min in 39 (44.82%), 30-45 min in 6 (6.9%) and 45-60 min in 8 (9.2%) cases. The time taken for the interventions is represented in table 6.

Table 6: Time taken for the interventions

Time taken (min)	Number of interventions	Percentage (%)
0-15	34	39.08
15-30	39	44.82
30-45	6	6.9
45-60	8	9.2
Total	87	100

DISCUSSION

Drug-related problems are relatively common in neonates and can result in patient morbidity and mortality, and increased costs. The number of drugs used and the number of clinical/pharmacological risk factors significantly and independently influenced the risk for medication-related errors[3]. In India, clinical pharmacy service is an emerging discipline. Clinical pharmacy service is to optimize patient outcomes by working to achieve the best possible quality use of medicine.

Among the 150 patients followed during the study period, 80 patients were found to need pharmacist intervention in their drug therapy. A total of 87 drug related problems was identified and assessed from 80 patients. Out of 80 patients involved in drug-related problems, 52 (65%) were males and 28 (35%) were females. This study showed a high incidence of drug-related problems in males over females. This might be due to increased medication use owing to their multiple Comorbidities. Their mean birth weight was 2.316 kg (range = 0.6-4.4 kg) and mean gestational age was 35.55±3.467 w (range = 24-40 w). This observation is similar to the demographic reports of the studies conducted by *Lerner RB et al.*[4] and *Schellack N et al.*[5].

Most of the pharmacist-initiated interventions carried out in this study resulted from Dose/frequency inappropriate (40.22%) followed by Administration errors (31.05%) and Drug Interactions (17.24%). Most of the Administration errors encountered were Transcription errors (13.80%), Dosing administration errors (5.75%), Time of administration errors (5.75%), Dilution errors (3.45%) and Duration of administration errors (2.30%). This finding is consistent with the study carried out by *Struck P et al.*[6] which showed that most interventions involved were dose/frequency inappropriate (46.8%) followed by Administration errors(20.9%). This observation is also similar to the study conducted by *Simpson JH et al.* [7]and *Jain S et al.*[8] where the dosing errors were the commonest form of detected errors. This observation is in contrast with study performed by *Stavroudis TA et al.*[9], in which the human factors were the most frequently cited errors followed by administration errors. The study carried out by *Kaushal R et al.[10]* showed that incorrect dosing was the second most common medication-related problem observed, but in our study, Dosing errors accounted for the highest medication-related errors. According to the study carried out by *Ganachari MS, et al.[11]*, the majority of clinical pharmacist recommendations were on drug choice (48.64%). In this study the major reason for the dose/frequency inappropriate were due to the prescription-related errors in the dose calculation on the basis of birth weight and gestational age and also due to the busy schedule of the physicians in the Neonatal Intensive Care Unit. In most case recommendations on dosing were sought in dose too high, dose too low and in patients with renal impairment requiring dosage reduction. Administration errors, second most reported errors in this study may be due to the lack of rechecking the correct dose and frequency by the concerned nursing staff before administering the drug to the patient. While in few other cases, it was due to the nurses working overload and also due to shift change of nursing staff. Drug interactions accounted for 17.24% of medication errors identified which incorporated more of the drug-drug interaction (93.33%) followed by drug-disease interaction (6.67%). The addition of a new drug (3.45%) was suggested in the case of drug needed not prescribed. The major reason for drug discontinuation was due to drugs prescribed not needed and also due to the adverse effects appeared during the administration of the drug. And the adverse effects and Contraindications/drug inappropriate were accounted for 3.45% and 2.30% respectively.

One of the major interventions made in the problems occurred due to the adverse effects was Vancomycin-Induced Redman Syndrome. This adverse effect was observed due to the incorrect rates of administration (infusion over 30 min) of vancomycin by the nursing staff. This was corrected by slower infusion rates (60 min) of vancomycin, which prevented or reduced the syndrome. This emphasized the fact that the rate of administration is an important determinant of red man syndrome in susceptible cases[12]. These finding in this study indicate that there is a scope for clinical pharmacists to suggest issues related to rational drug therapy and an emphasis on the importance of involvement of pharmacist in health care delivery.

The test of proportions was used to evaluate the interventions between In-born and Out-born patients (table 2.), Patients admitted with or without additional surgical care (table 3), and Preterm-Term patients (table 4). A low *p*-value (<0.001) indicates that the proportion between inborn and out-born populations is significant at the 0.1 % level of significance. Further, a high proportion of 0.772 shows that the out-born babies need a number of interventions. But in the case of patients admitted with or without additional surgical care, *p*-value is greater than the significance value 0.05, so we conclude that the proportion between two groups of populations is not significant at the 5 % level of significance. In the case of preterm or term patients, *p*-value is greater than the significance value 0.05, which showed that the proportion between two groups of populations is not significant at the 5 % level of significance. The finding in this study is in contrast with the study carried out by *Lerner RB et al.*[4] which reported that the incidence of medical errors was significantly higher in newborn infants with lower gestational age.

The acceptance rate of intervening clinical pharmacist recommendation and change in drug therapy was found to be high (68.97%). There were (20.69%) other interventions where

suggestions were accepted, but therapy was not changed either because the physicians were hesitant to change the prescription immediately, without close monitoring, or because the suggestions were thought to be insignificant. Only 10.34% of the suggestions were neither accepted, nor therapy changed. One of the reasons for this could be that the pharmacist's failed to understand the sophisticated prescribing behavior, i.e. prescribing decisions governed by the clinical experience of physicians

These findings in this study correlate with the study carried out by *Dr. Head YH, et al.[13]*, cited that 83.7% of the pharmacist's suggestions were accepted with changes and 9.9% were not accepted. As per the study done by *Ganachari MS, et al.[11]*, the acceptance rate of recommendation and change in drug therapy was found to be high 78.37%. These findings are almost similar to the study conducted by *Struck, P et al.* [6]which showed that the physician acceptance rate of the interventions with or without changes was 87.3%. In our study, the physician acceptance rate with or without changes was found to be 89.6%.

While analyzing the time taken for the interventions, (39.08%) interventions took 15 min or less to complete and 44.82% interventions took 15 to 30 min to complete. This reflects the high number of problems to resolve in a limited amount of time. The main aim of the clinical pharmacist was to see the maximum number of patients possible, prioritizing their problems to ensure that those in need receiving the highest level of care.

Consequently, a large number of patients are seen, and problems were resolved quickly wherever possible. It should be noted that (6.9 %) of the interventions took 30-45 min to complete and (9.2%) of the interventions took 45-60 min to complete reflecting the complex nature of some of the problems encountered. This finding in the study is in contrast with the study performed by *Struck, P et al.* [6]where in 90% of the interventions took 10 min or less to complete. This difference may be attributed to the fact that the involvement of an experienced clinical pharmacist would have led to the high acceptance rate and also reductions in time spend for each intervention.

Of the 87 pharmacists initiated interventions, 55.17% were rated to be 'moderate', 33.33% were 'minor' and 11.49% were 'major' significance of interventions. This observation in our study correlates with the study performed by *Ganachari M S, et al. [11]*, which cited that most of the pharmacist interventions were seen to have moderate significance in grade. This finding is in contrast with studies *[7, 14]* that reported that 3.8% and 1.5% of interventions as moderate significance respectively.

CONCLUSION

Medication errors are common in the neonatal intensive care unit (NICU). Most of the pharmacist-initiated interventions carried out in this study resulted from Dose/frequency inappropriate. Administration errors were the second most frequent type of intervention. The majority of the interventions involved were related to Antibiotics. The physician acceptance rate with or without changes was found to be 89.6%. This study demonstrates that the physician's acceptance rate of pharmacist intervention is high.

The success of a program such as this depends on pharmacists understanding the importance of documenting their interventions and that they are encouraged to do so. When intervening as a part of their clinical pharmacy services, pharmacists don't necessarily save lives, but can bring about changes, which directly increased the quality of patient care. By documenting these interventions, the value of clinical pharmacist's expertise in Neonatal patient care can be established.

CONFLICT OF INTERESTS

Declared None

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