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RISK AND COST ANALYSIS OF INJECTABLE MEDICATIONS IN PEDIATRICS

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ABSTRACT

Objectives Pediatrics is the specialty of medical science concerned with the physical, mental and social health of children from birth to young adulthood. "Injectable medication" means any medication administered by the intravenous, intramuscular or subcutaneous route. The aim of the study is to observe the risks of medications in pediatrics, health care staff vigilance and provision of child-centered care to pediatric patients in the different hospitals of Lahore. **Methods** A structured questionnaire was designed to collect data from 100 pediatric patients. The study also covers the limitations and risks associated with the administration of injectable medications, use of non-disposable devices, dose miscalculations and medication errors which occur due to inappropriate administration and wrong prescription orders. **Results** showed that in majority of subjects, risks during administration of injectable medication through intravenous route is local edema, erythema and bleeding from the site of injection. Pediatrics are more prone to the adverse drug reactions associated with dose miscalculations because intravenous route is the more direct route to distribute drug in systemic circulation. **Conclusion** It is concluded that the intravenous route is the most common and preferrable route for therapy of illnes, nutitional and electrolyte imbalance in pediatrics. Dose calculation and medication errors should be avoided which require proper vigilance by the pharmacist, physicians and other health care staff.

KEY WORDS: Injectable medication, Intravenous, Intramuscular, Subcutaneous, Pediatrics.

INTRODUCTION

Pediatrics is the specialty of medical science concerned with the physical, mental and social health of children from birth to young adulthood. Pediatric care encompasses a broad spectrum of health services ranging from preventive health care to the diagnosis and treatment of acute and chronic diseases [1] .Among pediatric subpopulations are new born (birth to 1 month of age), Infant (1 month to 2 years) and child (2 to 12 years), although the upper age limit used to define the pediatric population varies among experts [2].

An injection (often referred to as a "shot" in US english, or a "jab" in UK english) is an infusion method of putting fluid into the body [3], usually with a syringe and a hollow needle which is pierced through the skin to a sufficient depth for the material to be administered into the body. An injection follows a parenteral route of administration; that is, administration via a route other than through the digestive tract.

There are several methods of injection or infusion used in humans including intradermal, subcutaneous, intramuscular, intravenous, intraosseous, intraperitoneal, intrathecal, epidural, intracardiac, intra-articular, intracavernous and intravitreal. Injections are among the most common health care procedures with at least 16 billion administered in developing and transitional countries each year [3]. 95% of injections are administered in curative care, 3% are for immunization, and the rest for other purposes, such as blood transfusions [3].

In an intramuscular injection, the medication is delivered directly into a muscle. Many vaccines are administered intramuscularly, as are codeine, metoclopramide, and many other medications[3]. Many drugs injected intramuscularly are absorbed into the muscle fairly quickly, while others are more gradual. Injections to the buttocks are known to reach the bloodstream quickly due to the large amount of muscular tissue and corresponding blood supply.

A depot injection is an injection, usually subcutaneous or intramuscular, of a pharmacological agent which releases its active compound in a consistent way over a long period of time. Depot injections are usually either solid or oil-based.In psychiatric nursing, a short acting depot, zuclopenthixol acetate (Clopixol Acuphase), which lasts in the system from 24 – 72 hours, is now more regularly used for rapid tranquillization [3].

Intravenous injection is an injection made into a vein, it is used when rapid absorption is called for when fluid cannot be taken by mouth or when the substance to be administered is too irritating to be injected into the skin or muscles. In certain diagnostic tests and x-ray examinations, a drug or dye may be administered intravenously. The intravenous route is the most common route for administration in pediatrics and fastest way to deliver fluids and medications throughout the body. The bioavailability of medication is 100% in IV therapy [4].

Intravenous infusion is usually given in the arm through t he median basilic or median cephalic vein but veins at various other sites may be used. The vein must be exposed if a cannula is used. Introduction of solution should be at the rate required to deliver the needed amount of fluid and contained electrolytes, medicines, or nutrients in a prescribed time[5]. The most preferred sites used in the pediatrics are through upper and lower arm veins, foot vein, scalp vein, thigh and buttock [5]. The Pain of an injection may be lessened by prior application of ice or topical anesthetic, or simultaneous pinching of the skin.

Viruses such as HIV and hepatitis C are prevalent among IV drug users in many countries, mostly due to small groups sharing injection equipment combined with a lack of proper sterilization. Other health problems arise from poor hygiene and injection technique (IV, IM, or SC), such as cotton fever, abscesses, vein collapse, ulcers, malaria, gas gangrene, tetanus, septicaemia, thrombosis, embolism. The Problems which arise in pediatrics mainly are air embolism, erythema, rash, urticaria, bleeding, cyanosis and localized edema [6].

Recent surveys showed that 30% of immunization injections are unsafe, and that 50% of all injections administered may be unsafe in some parts of the world. Although the threat of HIV or hepatitis transmission is particularly worrying, all injections can carry a risk. Injections can cause the spread of both viruses and infections if the syringe and needle are not sterile Accidents can also happen, resulting in abscesses, cuts or scratches. For small children, injections can carry a special threat, including the risk of provoking paralytic poliomyelitis [7].

40% of injections worldwide are administered with unsterilized, reused syringes and needles, and in some countries this proportion is 70%, exposing millions of people to infections. Many countries have legislation or policies that mandate that healthcare professionals use a safety syringe or alternative methods of administering medicines whenever possible[3].

Unsafe injection practices have a wide range of causes: Training of health workers may be lacking or has not sufficiently emphasized the risks of unsterile injections; Injection equipment is expensive and when resources are scarce, the disposal of syringes and needles appears wasteful. In some cases supplies are short and insufficient to meet the needs, leading health workers to "cut corners" and reuse disposable equipment. The cost of safety rises in the last 10 years, concern for safety has driven the introduction of disposable syringes [7]. This has increased the cost per injection. In addition to the cost of the syringe, the cost of disposal at the point of use is often neglected. The "high" cost of safety, which is rarely compared to the cost of cross infection, is undoubtedly one of the main impediments to any serious tackling of the problem.

The study aims to focus on risk and cost analysis of injectable medication therapy in pediatrics, health care staff vigilances and provide child-centered care to patients and their parents.

In pediatric medicine, drug doses are usually calculated individually based on the patient's age, weight and clinical condition. Therefore, there are increased opportunities for, and a relatively high risk of, dosing errors in this setting. Major studies found that dosing errors are the most common type of medication error in the pediatric population. The information available shows that dosing errors are not uncommon and that 10-fold overdoses caused by calculation errors have led to serious consequences [8]. The main interventions found were computerized physician order entry and computer-aided prescribing. Most computerized physician order entry and computer-aided prescribing studies showed some degree of reduction in medication errors. Interventions to reduce the risk of dose calculation errors are therefore urgently needed. Unit dose dispensing systems and educational/risk management programmes were also shown to reduce medication errors in children. Although it is suggested that 'smart' intravenous pumps can potentially reduce infusion errors in children [9].

IV Phenytoin at 20 mg/kg rather than 18 mg/kg is recommended. This will make the calculation easier and reduce the risk of significant errors. Ease of dose calculation without an electronic calculator should be taken into account when making recommendations for drug doses in children, especially those to be used in emergency situations [10]. For many drugs to be used in children, safe dosages which are fractions of those normally given to adults must be calculated. Determining pediatric dosages can be complicated because of the need to calculate them according to the child's weight; therefore, those children who take such medications are at greater risk for medication error than others who take medications that do not require such calculations. If no calculation is required, the risk of an error decreases significantly.

Almost all pediatric medications require the clinician to perform a mathematical calculation, one that may be complex. The most common calculations involve fractions, percentages, decimals, and ratios. In

mathematical tests, new interns and nurses have been found to have poor mathematical skills. Nurses have demonstrated the best computational skills than physicians and pharmacists [11].

Medication errors are causing significant harm to hospitalized patients with high economic implications; the risk is particularly high in intensive care units. Pediatric patients need weight-based dosing, which necessitates more calculations than for adults. Previous studies have identified an error rate of 13–84% in hospitals when preparing and administering intravenous drugs to infants and children. Dose calculations are a common contributor to medication errors, with a factor 10 error being among the most common [12].

The medication process of injectables was split up into five major steps such as prescription, transcription, preparation, administration and storage. The use of a prospective risk analysis has allowed a quantitative evaluation of the safety of pediatric patients in connection with the injectable medication process. The generating tools for the continuous safety improvement by modeling the relative safety gain for specific tools or new developments. Based on a pharmaco-economic analysis in a local setting, the involvement of a clinical pharmacist and the introduction of ready-to-use syringes for selected drugs have been shown to be the most cost-effective tool [13].

Floor et al suggested that introduction of computerized physician order entry systems clearly reduces medication prescription errors; however, clinical benefit of computerized physician order entry systems in pediatric or intensive care unit settings has not yet been demonstrated. The quality of the implementation process could be a decisive factor determining overall success or failure. It has been shown that computer support in drug dosing has resulted in more patients with drug concentrations in the therapeutic range, reduced time to achieve therapeutic benefits, and resulted in fewer adverse effects of treatment in adults [14].

Aspiration prior to injection is just one part of the process of performing vaccinations, therapeutic injections and diagnostic/therapeutic procedures. Injections given for the purpose of routine immunizations are different from injections for medications. The minimal risk of side effects combined with defined sites for immunization form one basis of the existing recommendations for eliminating aspiration during immunization. If the drugs to be given have potentially fatal consequences in the event of systemic administration (as in the case of immunotherapy) all possible precautions must be taken. This is all the more important in cases where the drug is being administered electively by specialist staff. On the other hand, if there are no serious known sequelae to a drug being injected systemically – as in the case of vaccines – an argument can be made not to aspirate, especially since a huge number of immunizations are performed globally by vaccinators and health workers. A systematic approach would be to conduct randomized controlled trials of the device to reach an unbiased conclusion on the benefits and necessity for aspiration using therapeutic re-use prevention syringes and AD syringes for vaccinations; the appropriate duration of aspiration that yields best results also needs to be determined. If such trials deem that aspiration should be part of the recommended therapeutic and vaccination technique, this would act as the driving force for the device industry to develop appropriate tools to meet these requirements [15].

The most frequently reported medication errors were: overdose, wrong drug, and wrong patient and improper route of administration. Physicians and nurses were involved almost equally often in the errors, with some prevalence of nurses owing to their part in the drug administration process. Every fifth reported case of wrong regime of medication or wrong drug application was associated with improper recommendations or with drug dispensing errors.

The most serious consequences for patients' health were related to overdoses of drugs administered via the intravenous route [16]. Children less than 5 years of age treated with pharmaceuticals affecting the central nervous system were exposed to a higher risk of serious health problems and death due to a medication error. Thus, special attention and precautions are appropriate when administering Phenobarbital, neostigmine, ketamine, and midazolam in pediatric practices [16].

Serious pediatric computer-related errors are uncommon, but computer systems can introduce some new pediatric medication errors that are not typically seen in a paper ordering system. 4 types of computer-related errors were identified: duplicate medication orders (same medication ordered twice in different concentrations of syrup, to work around computer constraints; 2 errors), drop-down menu selection errors (wrong selection from a drop-down box; 9 errors), keypad entry error (5 typed instead of 50; 1 error), and order set errors (orders selected from a pediatric order set that were not appropriate for the patient; 8 errors). In addition, 4 preventable adverse drug events in drug ordering occurred that were not considered computer-related but were not prevented by the computerized physician order entry system [17].

Although there is a growing national focus on health care cost containment and accountability in resource utilization, childhood cancer therapy costs continue to increase without proportionate survival improvements. Economic evaluations such as cost and/or cost effectiveness analysis may identify areas to improve resource efficiency.

The results of this review demonstrate the significant opportunities for economic evaluations of treatments of the childhood cancer. Incorporating indirect cost

estimations and cost-utility evaluation may balance the health care and family perspectives if methodological issues are overcome. This review demonstrates an imbalance of tumor-directed therapy and supportive therapy evaluations. Tumor-directed treatments predict the toxicities encountered and needs for supportive therapies and likely have the largest economic impact. Pediatric oncology has made survival improvements through prospective clinical trials performed in collaborative networks. Applying economic evaluations tools to tumor-directed therapies in a systematic and objective manner in collaboration within these networks could lead to more efficient use of limited resources [18].

MATERIALS AND METHODS

Study design

An observational study was conducted during June 2015 to August 2015 in various hospitals of Lahore, Pakistan.

Inclusion and exclusion criteria

Pediatric patients treated with any type of injectable medication process were included while pediatric patients treated with medication process other than Injectables and patients other than pediatrics were excluded.

Data collection procedure

A questionnaire was developed to obtain data regarding the safety of medications for children, appropriate dose requirements, prevention & reporting of pediatric medication errors by using Injectable medication processes and cost analysis of all the Injectables medication process. Collected Data was analyzed and the results were presented in tabular and graphical form.

Ethical approval

The study was approved by Institute of pharmacy, Lahore College for Women University, Lahore, Pakistan and also from selected hospitals.

RESULTS

A total of 100 subjects were observed in the indoor wards of different hospitals in Lahore. Results showed that majority of the pediatric patients have found to be suffered from severe diseases needing the therapy via administration of injectable medication process (Fig1) and for all of the pediatric patients, administration via injectable route was necessary for their treatment (Fig 2). Results further indicated that in all of the pediatric patients, mostly intravenous route was used (Fig 3). It was found that there was an equal incidence of administering the injectable medications by only one route (IV) and in combination with other routes (Fig 4). Moreover, mostly oral route is used in combination with Injectable route (Fig 5). In majority of the pediatric patients, medication was administered through arm (upper / lower) vein and to less extent through foot vein (Fig 6). Majority of the pediatric patients faced the local edema due to administration via injectables while some of the patients faced erythema and bleeding (Fig 7). In majority of the cases, disposable injectable devices were used for the treatment of pediatrics (Fig 8).

It was further noted that for majority of patients, dose calculation was done before injectable administration in accordance with their weight and age (Fig 9). In majority of the pediatric patients, the risks were due to the improper use of catheter or branula while the risks due to the use of drugs and non- disposable devices were rare (Fig 10) and majority of the pediatric patients suffered from no medication errors (Fig 11). However, in fewer cases, medication errors occured due to wrong administration and very few due to wrong prescription (Fig 12). In most of the hospitals free facilities were provided to the pediatric patients, due to which, the cost of the therapies contributed by the parents was not high (Fig 12).

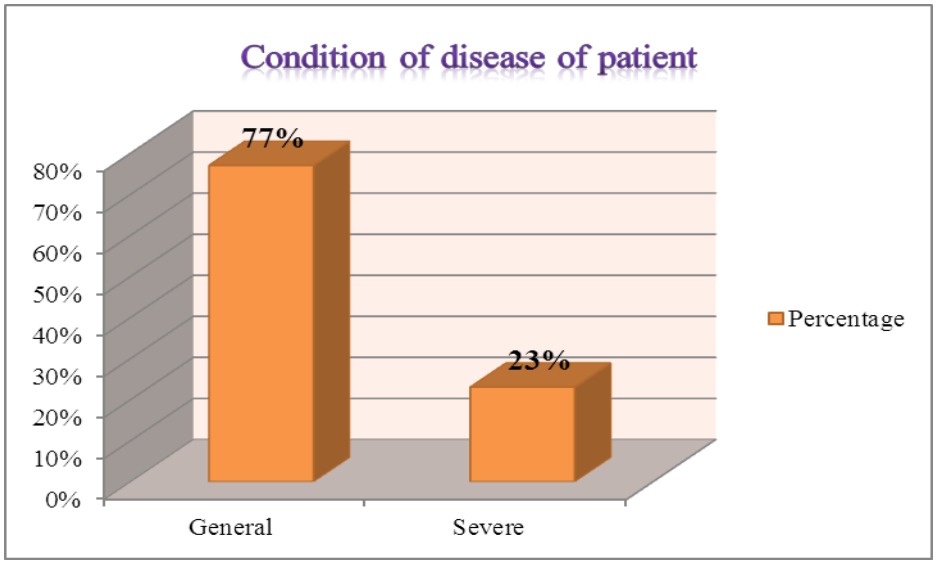

Fig 1: Condition of the disease of patient.

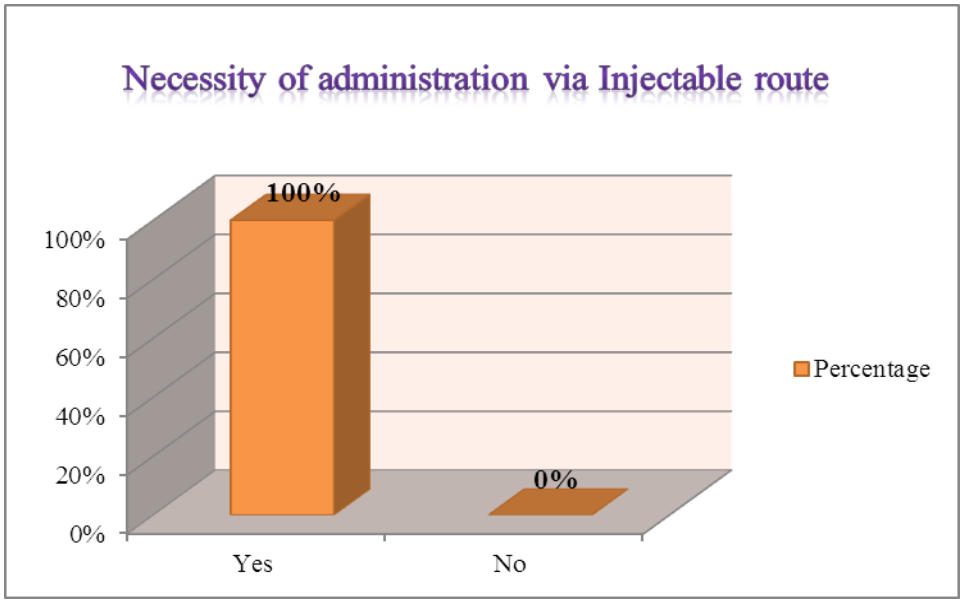

Fig 2: Necessity of administration via injectable route.

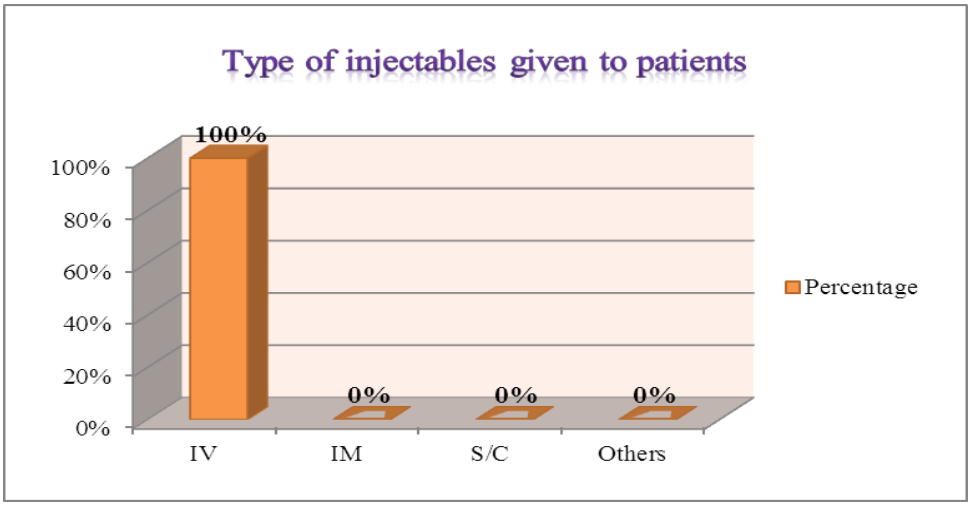

Fig 3: Type of injectables given to patients.

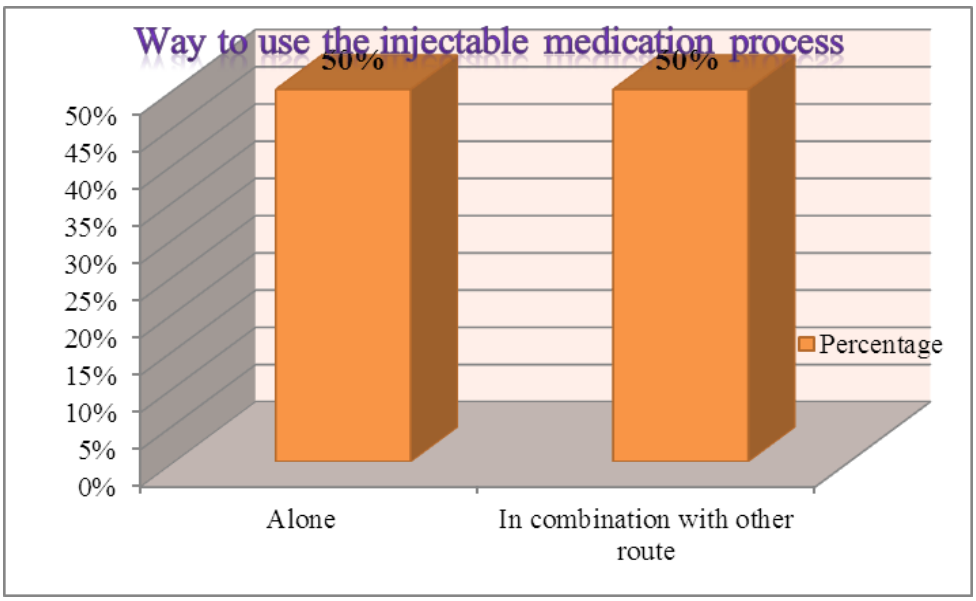

Fig 4: Way to use the injectable medication process

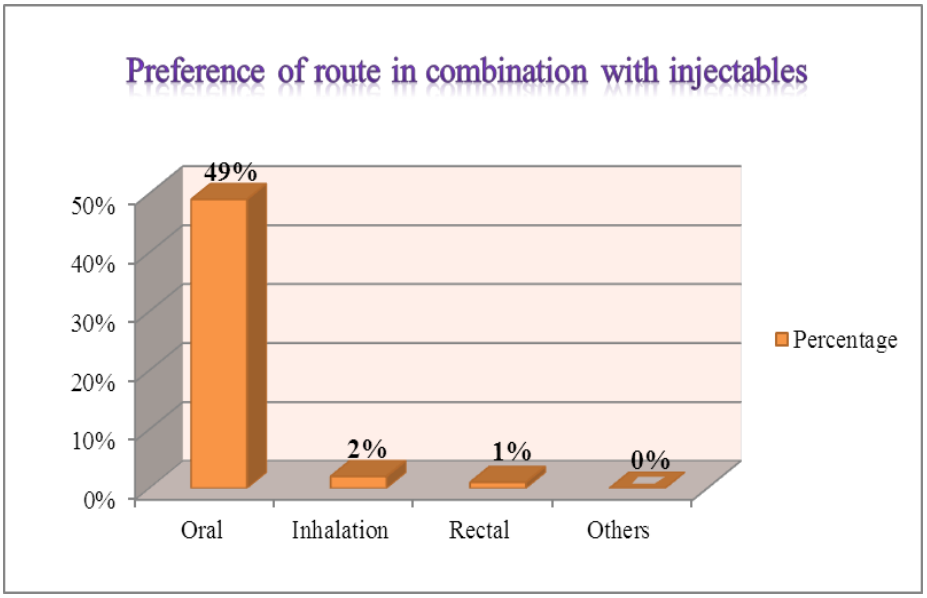

Fig 5: Preference of route in combination with injectables.

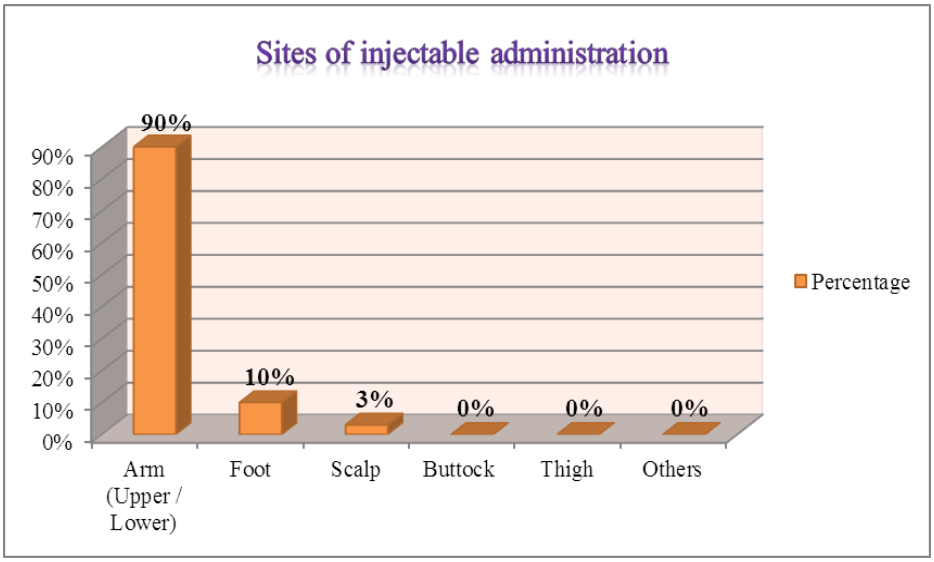

Fig 6: Site of injectable administration

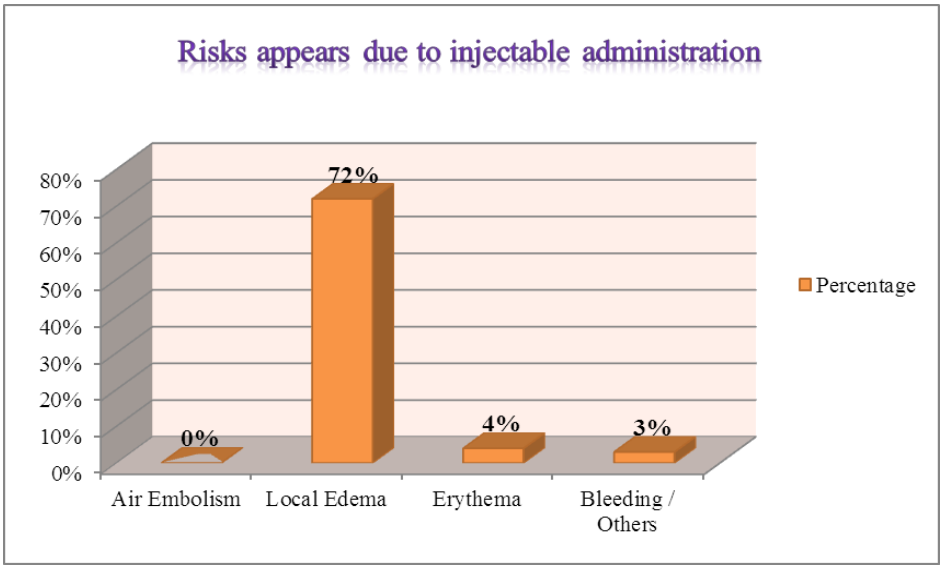

Fig 7: Risks appears due to injectable administration.

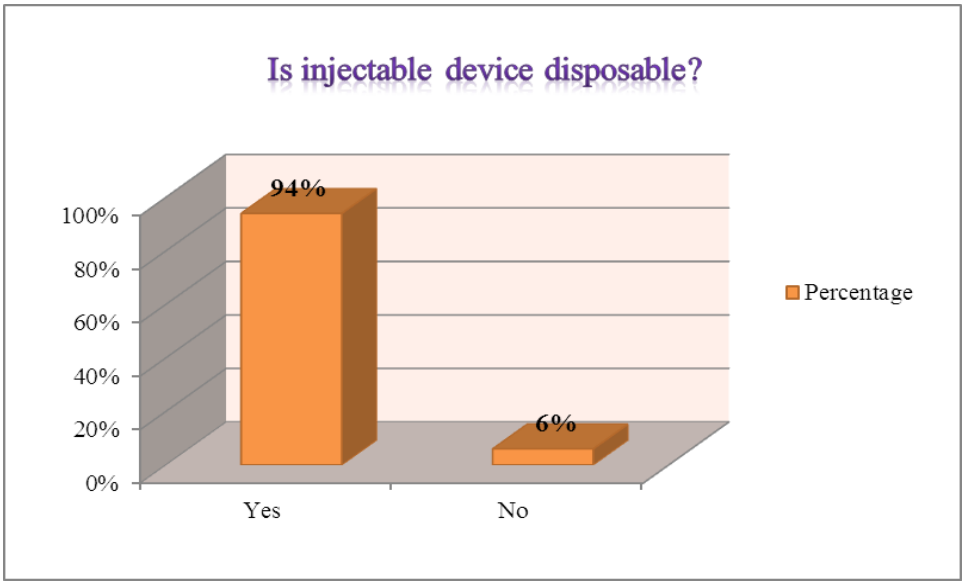

Fig 8: Is injectable device disposable?

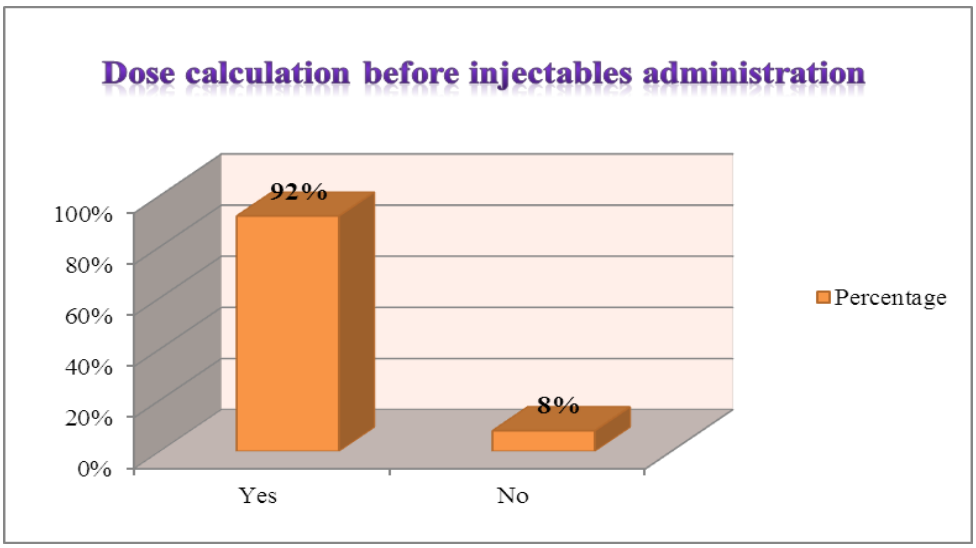

Fig 9: Dose calculation before administration

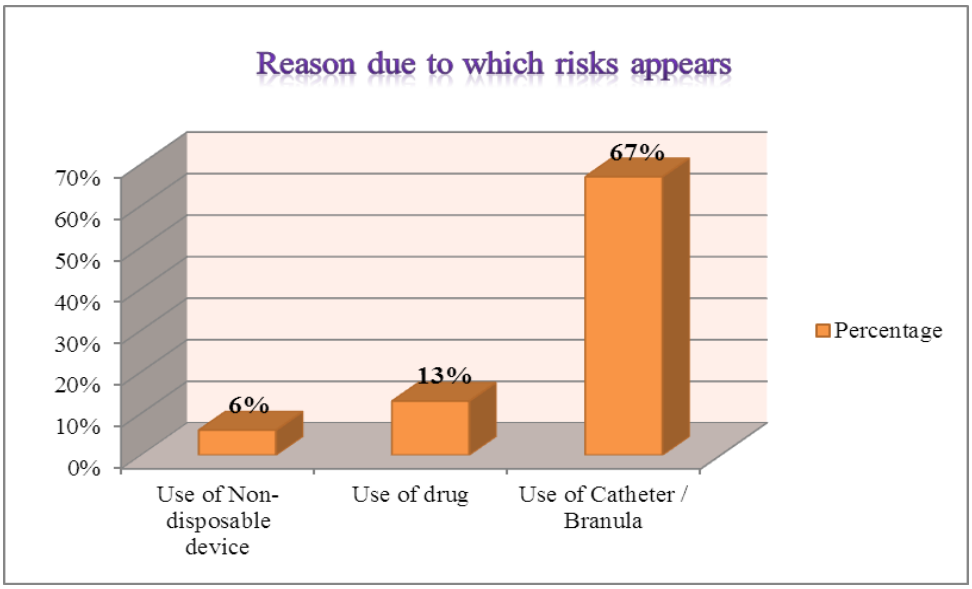

Fig10: Reason due to which risks appear.

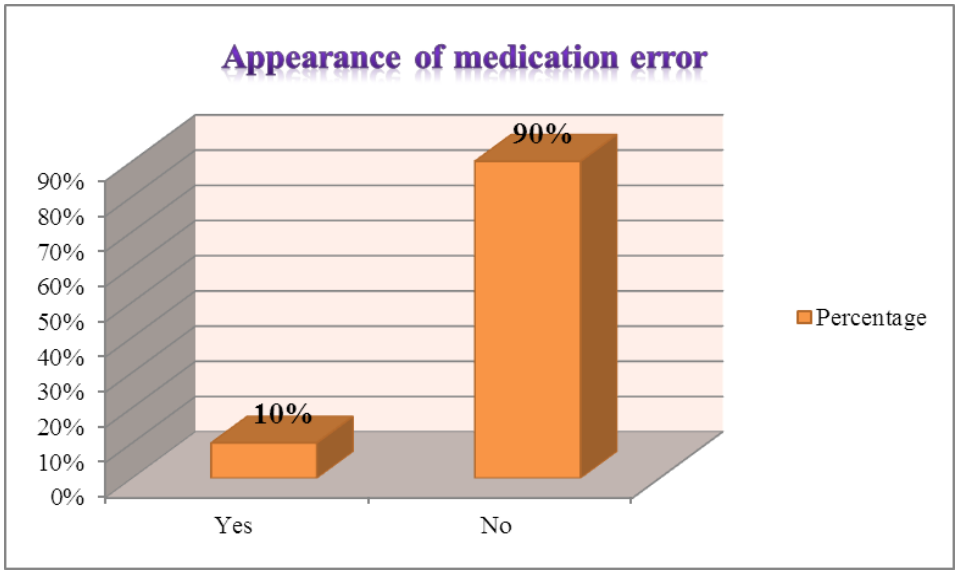

Fig 11: Is any type of medication error appears?

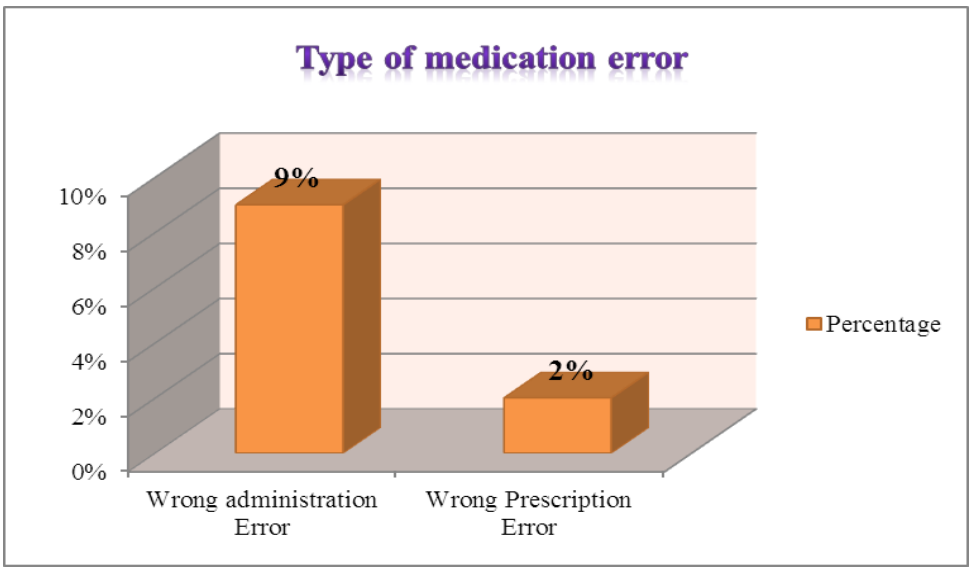

Fig 12: Type of medication error

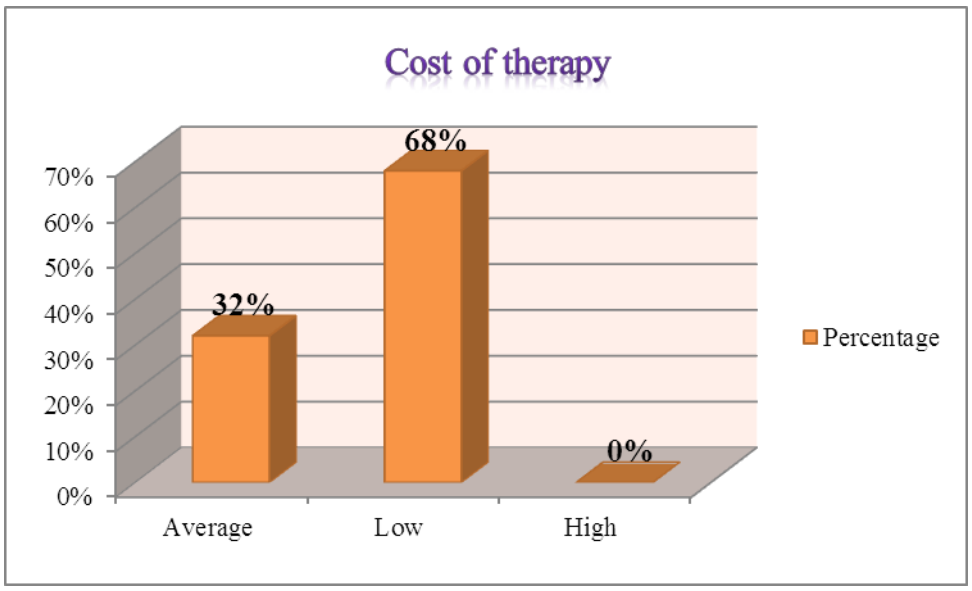

Fig 13: Cost of therapy

DISCUSSION

During survey at different hospitals in Lahore, pediatric patients were observed suffering from various diseases and treatment was given to them. They were given injecatable medications majorly via IV route of administration. Majority of patients had severe illness which require the administration of injectable medication processes in them due to rapid response or in a condition that they were unable to take medication orally. While to some patients, injectable therapy was given in combination with other routes, mainly oral route. Moreover, inhaltion and rectal route was also used in certain cases due to the condition and the requirement of the patient disease state.

The type of injectable medication process mostly used for administration of medication was intravenous because intravenous route is the most common and preferrable route for therapy of illnes and nutritional and electrolyte imbalance while subcutaneous annd intramuscular route of the administation was not prefferably used in pediatrics as these routes are difficult for administration in pediatrics.

Survey results depicted that the major site of injection was arm or forearm. Foot and scalp was also used due to safe administration and for ease of insertion of drug in pediatrics mostly in new born babies and very small children. While in certain cases intravenous therapy through scalp vein was preferred due to reason of continuous bleeding and certain other complicated conditions. Patients mostly faced local edema when having injectable therapy through IV route. Erythema and bleeding was also occurred due to IV administration. These risks were mainly due to the use of catheters and butterfly cannula or branula, and to the less extent due to the use of inappropriate medicine and non disposable devices or disposable devices used for long time i.e; more than 3 days. But in most of the cases disposable injectable devices were used and used devices changed with a new one after one day mostly.

As pediatrics are more prone to the adverse drug reactions associated with dose miscalculations, medication errors must be avoided but suvey showed that a little bit negligence occured due to wrong adminstration (i.e; improper use of catheter / branula for IV administration) and given wrong prescription i.e. drug interaction. Majority of patients administered drug after the dose calculation in accordance with their weight and age by the medical staff and given proper attention for their dosing at minimum and effective concentraion of drug for pediatrics.

Survey population was satisfied by their physician and other health care staff attention and their curative treatment i.e; child centered therapy. But direct pharmacist-patient interaction or with their parents was lacking. The need of hour is to focus on the medication errors, specilly wrong administration error and wrong prescription errors, which can be avoided if there is an availability of pharmacist in wards for proper consultation and guidance related to administration and also for review of prescriptions. In most of the hospitals, free facilities were provided to the pediatric patients. So the cost of the therapies contributed by the parents was found to be low as the overall cost given by them is only dependent on their stay in health care vicinity. While in certain hospitals, parents are paid for the therapies given to their children regarding treatment as well as for their stay in health care vicinity.

CONCLUSION

Intravenous route is the most common and preferrable route for therapy of illnes and nutritional and electrolyte imbalance in pediatrics. Major risks which arise during administration of injectable medication through IV route is local edema, erythma and bleeding from the site of injection. These risks were mainly due to the use of catheters and butterfly cannula or branula, and to the less extent due to the use of inappropriate medicine and non disposable devices or disposable devices used for long time i.e; more than 3 days. Dose calculation and medication errors require proper vigilance by the pharmacist, physicians and other health care staff. In hospitals, free facilities should be provided to the pediatric patients, so that overall cost of the therapies given to them should be low or negligible.

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