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# THE USE OF AMPICILLIN AND AMPICLOX SOLUTIONS FOR PARENTERAL INJECTION IN THE PEDIATRIC WARD

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**ABSTRACT**

In our hospital, injectable ampicillin and ampiclox are available in one form only; vials containing 500 mg of the drug. When used for intravenous or intramuscular injection, these drugs are dissolved in 4-5' ml of distilled water or isotonic normal saline. If the recommended dose is 125-250 mg at a time, part of the dissolved drug is injected. The remaining part is not discarded, it is rather reused 6-8 hourly thereafter. This faulty attitude is contradictory to the scientific facts related to the stability of ampicillin and ampiclox solutions, that recommend the use of them within one hour of their dissolution and discarding the unused part. About three quarters of ampicillin users (72.27 %), and more than half of ampiclox users (54.87 %) were receiving the drugs in the faulty way, i.e. many hours after their dissolution. The study recommended that one of the following to be undertaken to bypass this therapeutic disorder:
(1) provision of vials containing 125250 mg of the drugs, or
(2) discarding the remaining parts of the dissolved drugs, or
(3) dissolving these two drugs in 20 ml of the diluent as they have a better stability at low concentration (8 hours), and if kept at the refrigerator (24-48 hours), or
(4) establishment of a full-time working pharmacy units to supply the wards with the amounts of ampicillin or ampiclox that are required for the patients, time by time, besides its provision of other sorts of drugs instead of lending them from the pharmacy of the casualty department at times of need. The study recommends as well infusing ampicillin solution slowly (10-15 minutes), as more rapid infusion may cause convulsive seizures.



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## INTRODUCTION

Most injectable antibiotics are supplied in vials containing the drugs in its powder form. When used for intramuscular (i.m.) or intravenous (i.v.) injections, they are dissolved using different sorts of solvents. The stability of the resultant drug solutions is quite different. Ignorance of the facts related to stability may lead to misuse of the drug and wastage of its therapeutic effects. Because of the embargo imposed on our country, ampicillin and ampiclox are supplied to our hospital in one injectable form only; vials containing 500 mg of the ingredient. When used for i.m. or i.v. injection the drug is dissolved by 4-5 mls of distilled water or isotonic normal saline (N.S.). If the pediatric patients' requirement is 500 mg or more at a time, one or more vials' contents are dissolved and injected. If the required dose, is less than 500 mg, e.g. 125 or 250 mg, part of the dissolved 500 mg of ampicillin or ampiclox is injected, but the remaining part is not discarded or used to inject another patient. It is, rather, kept beside the patient to be reused 6-8 hourly thereafter, a trend that has been adopted for the last few years to avoid missing the drugs if they are kept within hands other than the patients' or his accompanies'.

**Aim of the Study:** To study the way of ampicillin and ampiclox dissolution and use in the pediatric ward, and to identify the size of the problem of injecting these drugs solutions long time after their dissolution.

## MATERIALS AND METHODS

Pediatric patients who were prescribed ampicillin or ampiclox in the ward were traced by revising some of the records of in-patients that were admitted during the preceding twelve

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months through 2001-2002. One and half months were chosen from each of the preceding seasons to avoid the seasonal variations in ampicillin use. From the revised records, those who used 500mg or more 6-8 hourly, and those who used a smaller doses of 125-250 mg 6-8 hourly were counted. The same was done in regard to ampiclox users.

## RESULTS

Of 4315 patients who used ampicillin, 3248 (75.27%) were using small doses of ampicillin (i.e. <250 mg per dose) provided to the patient by dissolving ampicillin and giving it in fractions.

**Table 1. The number of patients who used small doses of ampicillin and ampiclox that are made by dissolving 500 mg of the drug and using it long time after its dissolution**

| Months | Ampicillin users | | | Ampiclox users | | |
|---|---|---|---|---|---|---|
| | Total no. No. of Ampicillin users | No. of patients using small doses | % of small dose users | Total no. of Ampiclox users | No. of patients using small doses | % of small dose users |
| June | 1132 | 989 | 87.36 | 465 | 230 | 49.46 |
| $1/2$ July /2002 | 566 | 494 | 79.27 | 232 | 115 | 47.41 |
| April | 523 | 374 | 71.5 | 677 | 369 | 54.5 |
| $1/2$ March /2002 | 382 | 256 | 61 | 571 | 254 | 44.48 |
| January | 636 | 390 | 76.67 | 595 | 248 | 66.07 |
| $1/2$ December /2002 | 320 | 190 | 66.8 | 250 | 120 | 43.96 |
| October | 506 | 388 | 61.32 | 2146 | 1418 | 41.68 |
| $1/2$ September /2002 | 250 | 167 | 59.37 | 414 | 182 | 48 |
| Total | 4315 | 3248 | 75.27 | 5350 | 2936 | 45.87 |

**Table 2. Ampicillin Sulindac stability in different solutions (physician GeneR 1996)**

| Solution | Concentration | Stability at room temperature (70- 75 F) | Stability at refrigerator (9F) |
|---|---|---|---|
| Distilled water | <30 mg/ ml | 8 hours | 48 hours |
| | <20 mg/ml | 8 hours | 72 hours |
| Sodium chloride (N.S.) | <30 mg/ ml | 8 hours | 48 hours |
| | <20 mg/ml | 8 hours | 72 hours |
| Dextrose 5% | <20 mg/ml | 2 hours | 3 hours |
| Dextrose 5% in 0.45% NaCl | <10 mg/ml | 2 hours | 3 hours |
| Lactated Ringer | <30 mg/ml | 8 hours | 24 hours |

**Table 3. The required amount of solvents to have high concentrations of ampicillin sodium**

| Amount of ampicillin | Required amount of solvent | Total amount of the solution | Concentration of ampicillin |
|---|---|---|---|
| 1gm | 3.5ml | 4ml | 250mg/ml |
| | 7.4ml | 8ml | 125mg/ml |
| 2gm | 6.8ml | 8ml | 250mg/ml |

**Table 4. The amount of diluent used to achieve low concentrations of ampicillin**

| Amount of ampicillin sodium | Amount of diluent | Concentrations |
|---|---|---|
| 500 mg. | 50 ml. | 10 mg./ml. |
| | 100 ml. | 5 mg./ml. |
| 1gm. | 49 ml. | 20 mg./ml. |
| | 99 ml. | 10 mg./ml. |
| 2gm. | 99 ml. | 20 mg./ml. |

**Table (5). Stability of ampiclox solution, in low concentrations, with different sorts of solvents at room temperature and at refrigerator. i.v. fluid Stability period Stability at room period at temperature refrigerator**

| i.v. fluid | Stability period at room temperature (in hours) | Stability period at room refrigerator (in hours) |
|---|---|---|
| N.S. (0.9%) | 24 | 24 |
| Dextrose (5%) | 2 | 24 |
| Dextrose (9%) in saline (0.18%) | 2 | 24 |
| Ring solution | 24 | 24 |
| Sodium bicarbonate (1.4) | 4 | 6 |
| Dextran 40 (10%) in saline (0.9%) | 6 | - |
| Dextran 40 (10%) in dextrose (5%) | 2 | - |
| Sodium lactate | - | 6 |

In regard to ampiclox, 2936 patients (54.87%) of 5350 patients were using small doses of ampiclox (< 250 mg per dose), (Table 1).

## DISCUSSION

The stability of solutions of ampicillin sodium is dependent on many factors including concentration, pH, temperature and the nature of the vehicle. Stability decreases in the presence of glucose, fructose, dextrose, sodium bicarbonate and lactate (Martindale 2001). Stability studies demonstrated that ampicillin sodium in high concentrations (125 mg/ ml and 250 mg / ml) maintain their potencies up to one hour (Physicians GenR 1996). It is recommended that reconstituted solutions of ampicillin sodium for injection should be administered immediately after preparation and should not be frozen (Martindale 2001). For i.v. use it is recommended to dissolve 1 gm of ampicillin sodium in 3.4-7.4 ml to achieve a concentration of 250 mg /ml and 125 mg /ml consecutively. For 2 gms, 6.8 mls are recommended to be used for dissolution to have a concentration of 250 mg/ml (See table 3). In these concentrations' ampicillin should be administered slowly over 10-15 minutes. More rapid administration may result in convulsive seizures. Unused portion of any solution must be discarded after the recommended time period (physician gen R 1996). At a lower concentration (10-30 mg / ml), ampicillin sodium remains stable for longer periods, that vary according to the type of the used solvent and the temperature. For example, at room temperature, ampicillin sodium dissolved in distilled water, normal saline (N.S.), or lactated Ringer, in a concentration of 30 mg / ml or less remain stable for 8 hours, while in refrigerator (9 F) it remains stable for 24-72 hours. When dissolved in dextrose solutions, lower concentrations dose not improve the stability too much. At room temperature it becomes 2 hours and in refrigerator it remains the same. (See Table 2). In low concentrations, the stability is more prolonged (see Table 2), that is why continuous i.v. infusions can be used. Concentrations should not exceed 30 mg / ml due to concentration- dependent stability restrictions. Sodium chloride (0.9 %) is the diluent of choice for i.v. piggyback use. Standard diluent is 500mg / 50 ml N.S. or 2 gm / 100N.S. Lidocaine hydrochloride of 0.5-2 % concentration can be used for i.m. injections within 1 hour of preparation (UTD9.1 2001). In contrast to injectable solutions, oral suspension of ampicillin is stable for 7 days at room temperature or for 14 days under refrigerator (UTD, 9.1, 2001).

Ampiclox is compatible with commonly used i.v. fluids, but should not, however, be mixed with blood products or proteinaceous fluids nor with lipid emulsions (MEPPO, 1987). The period of stability at room temperature are shown in Table 5. Solutions should be used within one hour of preparation (MEPPO 1987). For i.v. infusions for bolus therapy, the vials content may be injected suitably diluted into a drip tubing. Alternatively, ampiclox may be rapidly infused over a period of 30- 49 minutes or added to infusion solution if necessary (MEPPO 1987).

**Conclusions**

In our pediatric ward, ampicillin and ampiclox solutions are used for i.v. or i.m. injection long time after its dissolution. This faulty practice is considerably detrimental and should be corrected in an appropriate way.

**Recommendations**

Many choices are available to combat the current misuse of ampicillin and ampiclox:

- Providing vials containing 125 mg and 250 mg of the drugs is the most ideal way to be undertaken.
- Discarding the remaining portion of the drug after its dissolution.
- Making low concentrations of the drugs by dissolving them in 20 ml of N.S. or distilled water using 20 ml syringes for this purpose. Such a solution if kept in refrigerator may remain stable up to 48 hours.
- Estimating the total amount of ampicillin or ampiclox that is required by the total number of pediatric patients each 6-8 hours and providing it, time by time, to be dissolved and injected so that nothing of the dissolved drug remain after its dissolution. This necessitate the establishment of a pharmacy unit that work although the day.

## REFERENCES

Martindale, the Complete Drug Reference, 2001: 153.
MEPPO, the Middle East Drug Reference, 1987: B;24 - 32.
Physician Gen R, the Complete Drug Reference, 1996; II: 118.
Up to Date, 9.1, 2001 (C.D.).

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