

COST EFFECTIVENESS OF LOCALLY MANUFACTURED ORTHOPAEDIC IMPLANTS

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ABSTRACT

Objectives: To study clinical outcome and cost effectiveness in patients treated with locally manufactured orthopaedic implants.

Type of study: Quasi experimental study

Time and Place of study: The study was conducted in department of Orthopaedic Surgery CMH Nowshera from Sep 2009 to Aug 2011.

Patients and Methods: All patients irrespective of age and gender, who were operated and applied orthopaedic implants, were included in the study. Good quality, cost effective locally manufactured orthopaedic implants were used in all cases. Clinical outcome was observed periodically and side effects like implant breakage, implant loosening and significant infection were recorded. Follow up period ranged from 6 months to 1 year. Descriptive statistics were used for data analysis.

Results: Total 123 patients completed the study and all had satisfactory clinical outcome and no case of implant breakage, implant loosening and significant infection was seen.

Conclusion: Locally manufactured implants can effectively be used without any significant side effects in place of costly branded counterparts.

Keywords: Orthopaedic implant

INTRODUCTION

Historically fractures were treated by closed means using different stiff materials to splint the dangling painful part of the limb. With the advancement in medical sciences the trend is shifting more and more towards internal fixation with orthopaedic implants. Material and design of these implants is a constantly developing area. However current generation of implants that works well is still not without problems in long term performance¹. Giants like SYNTHES, BIOMET etc are spending heavily on the research and development of these implants. The cost of these implants is very high and developing countries have to spend their valuable resources for import of these implants². The cost of these implants is affordable in developed countries but in a country like ours, it is out of range for the poor people. Some manufacturers in Pakistan are also making these implants and are in use all over the country. Although the city of Sialkot and surrounding areas are very famous for their surgical products and generally these are of

good standard, sometimes these are not properly standardized so quality varies from good to bad³. Use of implants of substandard quality causes problems due to many factors like corrosion and systemic absorption⁴. The implants used in our study include Austin Moore Prosthesis, Dynamic Hip Screw (DHS) system, Dynamic Condylar Screw (DCS) system, Intramedullary Interlocking (IM IL) nails, Dynamic Compression Plates (DCPs), Kirschner Wires (K-Wires) and screws. The purpose of the following study was to describe our experience with the locally manufactured implants.

MATERIALS AND METHODS

This quasi-experimental study was conducted at CMH Nowshera from Sep 2009 to Aug 2011. During the study period all cases that underwent operations with usage of implants were included in the study. All cases that were managed previously somewhere else were excluded from the study. Malunions and non-unions were also excluded from the study. A total of 123 cases were operated in which implants were used to fix the fractures. Only locally made implants were used from two manufacturers. (Fine ortho Enterprises and Treu dynamics). All implants were made of 316

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L stainless steel and the manufacturer has the certificate of this fact. All implants were thoroughly inspected and only good quality standard implants were accepted for use. Clinical outcome was observed periodically and side effects like implant breakage, implant loosening and significant infection were recorded. Average follow-up period for fracture cases was up to their union which averaged 6 months. Follow up was done on fortnightly basis clinically and on monthly basis radiologically. Operation site was especially looked for any redness, swelling or discharge. X-rays were examined for evaluation of radiological healing, state of fixation and condition of the implant. Follow up was continued till radiological union and return of optimal function of limb. For AM prosthesis the follow-up was continued for an average of one year. Data was analyzed using SPSS version 10. Descriptive statistics were used to describe the data.

RESULTS

A total of 123 cases were operated in which implants were used to fix the fractures. Age of the patients varied from 6 years to 80 years with median age of 32 years. Male to female ratio was 4:1. Description of implants is given in table 1. No implant breakage or loosening was observed during the follow-up period. No evidence of infection was observed in internal implants. Very mild pin-tract infection of K-wires was observed in 22 (17.9%) cases which settled after removal of the wires. In one (0.8%) case of IM IL nailing there was stitch abscess, which was treated successfully by drainage, antibiotics and dressings. In one (0.8%) case of tibial plating the wound gaped, causing partial exposure of DCP. The fracture healed well after which the plate was removed. Description of cost of different local and imported implants is given in table 2.

DISCUSSION

Orthopedic implants from well-known manufacturers like SYNTHES, ZIMMER and BIOMET remain the gold standard. But they have certain disadvantages in our setup like exuberant prices (Table-2), not readily available, non-availability of complete range especially in

Table-1: Distribution of local implants used.

Types of Implants	Frequency (%)
AM Prosthesis	16 (13)
IM IL Femoral Nail	9 (7.3)
DCS	3 (2.4)
DHS	15 (12.2)
IM IL Tibial Nail	11 (8.9)
DCP Narrow	4 (3.2)
DCP Small	13 (10.6)
Cortical Screws	3 (2.4)
DCP Broad	1 (0.8)
Cancellous screws 6.5mm	2 (1.6)
K-Wires	33 (26.8)
Cancellous screws 4mm	3 (2.4)
Malleable Wires	7 (5.7)
Ex-Fix	3 (2.4)

Table-2: Cost comparison of international and local brands

Types of Implants	Local Implants*	Imported Implants*
AM Prosthesis	6000	28000
IM IL Femoral Nail	5000	35000
DCS	3000	24000
DHS	3000	12000
IM IL Tibial Nail	5000	35000
DCP Narrow	700	4000
DCP Small	600	4000
Cortical Screws	100	900
DCP Broad	1000	8000
Cancellous screws 6.5mm	250	1300
K-Wires	100	465
Cancellous screws 4mm	150	600
Malleable Wires	200	1000

* Approx. price in Pak Rs.

small cities and towns. On the other hand because of the low price, the local manufacturers provide complete range on permanent basis that make your plans definite. This also avoids wastage of precious time. In our study we have observed that we did not face any significant problem with the use of these implants. However, we ensured that they were good quality locally manufactured implants and we individually checked out the quality of each implant before including it into our armamentarium.

Studies done in Pakistan have shown that most of the broken implants were locally

manufactured but this becomes insignificant when we consider that most of the implants used in Pakistan are locally manufactured and the examples shown in the study depicts that improper implants were used and there were shortcomings in the application of the implants⁵. Strict adherence to standards in manufacturing, handling and application of orthopaedic implants are important aspects for optimal results⁶. A study by Shoaib *et al* carried out in Pakistan has shown significant infection rate with orthopaedic implants⁷. We had very low incidence of infection because of proper cleansing and draping of the patient by the surgeon himself, proper sterilization of implants and equipment and use of pre-operative antibiotics. Another factor which improved our results significantly was controlled number of patients on any operation list. Maximum of two major orthopaedic cases are included in one operation list. The time of mobilization and weight bearing was very carefully determined according to the fracture pattern and state of healing.

CONCLUSION

Locally manufactured implants can be used effectively without any significant side effects in place of costly branded counterparts.

In a developing country like Pakistan where the economic condition of general population is poor, these implants can be very useful for the middle and lower class patients. It is further added that the musculoskeletal trauma is mostly the problem of this class of the society. Because of the possible inconsistency in quality by the local manufacturers each implant should be carefully inspected before adding into the range.

*There was no conflict of interest involved in this study.

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