

# Golden Wires and Rectangle: A Cost-Effective Treatment for Tuberculosis of the Thoracic Spine

## Abstract

**Study Design:** This was a retrospective study. **Purpose:** The purpose of this study was to compare the functional outcome and cost of surgery for tuberculosis (TB) of the thoracic spine between two commonly used fixation modalities “pedicular screws and rods” and “Hartshill loop rectangle and sublaminar wires.” **Overview of Literature:** TB is a common ailment in Asia. Surgical indications have remained almost unchanged since the middle-path regimen was advocated by Tuli. Pedicle screws and Hartshill loop rectangle with sublaminar wires are the two common fixation techniques used. **Materials and Methods:** This retrospective observational study was performed at a single tertiary center. Patients were divided into two groups depending on the method of fixation (pedicle screw rod/Hartshill loop rectangle and sublaminar wires). All patients were evaluated preoperatively by X-rays and magnetic resonance imaging. Patients were assessed clinically by preoperative and postoperative neurology and Visual Analog Scale score and radiologically assessed by the K angle. These variables were separately compared in both the groups. **Results:** The functional outcomes of Hartshill loop rectangle and sublaminar wire fixation and that of pedicular screw fixation were comparable. Hartshill loop rectangle and sublaminar wire fixation was found to be more cost-effective. **Conclusion:** Hartshill loop rectangle and sublaminar wire fixation gets purchase over the posterior column structures alone when compared to pedicle screws which have a 3-column hold. However, when combined with meticulous neural decompression and skillful preparation of osteogenic bed with autologous strut grafting and additional onlay grafting, it gives overall adequate stabilization of the column with functional outcome comparable to pedicular screw and rod fixation with additional benefit of cost-effectiveness. Although Hartshill loop rectangle and sublaminar wire fixation is less commonly used now, it has a special place in the management of TB, especially in a resource-poor setting like some countries of Asia.

**Keywords:** Hartshill loop rectangle, pedicle screw, sublaminar wires, tuberculosis

## Introduction

Spinal tuberculosis (TB) has been found in Egyptian mummies dating back to 3400 BC.<sup>[1]</sup> In 1779, Sir Percival Pott first described spinal deformity and paralysis due to TB;<sup>[2]</sup> hence, it is also known as Pott's spine.<sup>[3]</sup> Although pulmonary affection is the most common form of TB, extrapulmonary TB accounts for 15%–20% of all TB cases.<sup>[4]</sup> Among these, 1%–2% of patients have involvement of the skeletal system, with spinal TB being the most common form of skeletal TB, constituting about 50% of all cases.<sup>[5]</sup> Spinal TB is a very dreaded entity as it involves neurological complications, which occurs in 10%–43%<sup>[2]</sup> of cases. In spite of effective antitubercular drugs, there is a resulting sequel of kyphosis which needed to be addressed by surgical

intervention and metallic implants. The use of an implant is considered safe and is well accepted at present<sup>[6,7]</sup> under the cover of effective antituberculous chemotherapy Anti Tuberculous Treatment (ATT).

TB in a resource-poor setting like India and some countries of the Asian continent comes with its own set of socioeconomic issues. Majority of the patients are from urban slums and villages. Hence, providing a cost-effective treatment modality is of utmost importance.<sup>[8]</sup> Two of the commonly used implants for the treatment of spinal TB are “pedicular screws and rods” and “Hartshill loop rectangle with sublaminar wires.” The aim of the present study was to compare the functional outcome and cost-effectiveness of these two fixation methods.

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## Materials and Methods

Between January 2002 and December 2016, 186 consecutive patients with biopsy-proven thoracic spine TB underwent surgery at Seth GS Medical College and KEM Hospital, Mumbai, India. Retrospective analysis of the operation theater reports, patient records, and radiographs was done. Patients with healed post tubercular kyphotic deformity were excluded from this study. The presence of neurologic deficit (150 patients) and unstable vertebral column (36 patients) were the indications for surgery. Instability of vertebral column was defined as complete loss of >1 vertebral body with localized kyphosis of >30°, with or without coronal/sagittal plane translation. Patients with Frankel Grade C or D were treated by “middle-path regimen” popularized by Tuli.<sup>[9]</sup> This regimen involves treating patients by bed rest and chemotherapy for a minimum period of 3 weeks before being considered for surgery. Patients who fail to improve after 3–4 weeks of the “middle-path regimen” were considered for surgical intervention. Patients with severe neurological deficit (Frankel Grade A or B) underwent surgery as early as possible.

Demographic data including the patient's age, gender, vertebral levels involved, number of fused segments, bone type used for anterior reconstruction, preoperative and postoperative kyphosis angles (K angle), loss of correction at follow-up, preoperative and postoperative neurological status as assessed by Frankel grading, preoperative and postoperative pain assessed by the Visual Analog Scale (VAS) score, and postoperative complications if any were noted, and a case record form was prepared.

### Radiographic evaluation

All patients were evaluated by magnetic resonance imaging and X-rays. In patients with no ambulatory power in their lower limbs or those with imminent paralysis, supine radiographs were acquired. Anteroposterior and lateral radiographs of the thoracolumbar spine were performed postoperatively and during follow-up at 3, 6, 12, and 24 months. The K angle was calculated by drawing lines from the upper to the lower border of the first normal vertebra above and below the diseased area, respectively. Computed tomography scans were taken 1 year postoperatively for patients in whom fusion could not be assessed on X-ray.

### Statistical analysis

Descriptive statistics, including the means and standard deviations, were calculated for variables using SPSS software 17.0 (SPSS Inc., Chicago, IL, USA). The paired *t*-test was used to compare preoperative K angle and VAS score with postoperative values.

### Operative procedure

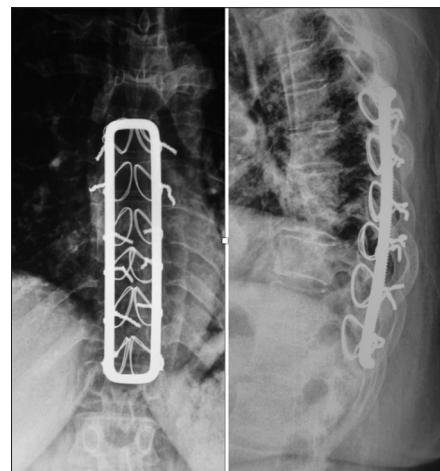
Patients were divided into two groups on the basis of the method of instrumentation. Group A consisted of

patients with instrumentation done within the thoracic spine segment in the form of Hartshill loop rectangle and sublaminar wires [Figure 1]. Single incision with combined anterior plus posterior exposure in lateral position (versatile approach)<sup>[10]</sup> was used. Group B consisted of patients with lesion in the thoracic spine requiring extension of fixation up to the upper lumbar spine. Instrumentation in the form of pedicular screw and rod system was done [Figure 2]. Posterolateral approach and decompression through a midline posterior incision was used.

Postoperatively, intermittent change of position while in bed was done to prevent pressure necrosis of wound. Drain removal was done after output became minimal. Mobilization with thoraco-lumbo-sacral orthosis (TLSO) was done post drain removal depending on the patients' neurological status and pain tolerance. Standing and walking were started once the patient regained ambulatory power. Intraoperative samples from all patients were sent for culture and sensitivity. Antitubercular treatment (ATT) was administered for 18 months as per the drug sensitivity. In cases of drug-resistant TB, ATT was administered for a longer period (2 years).

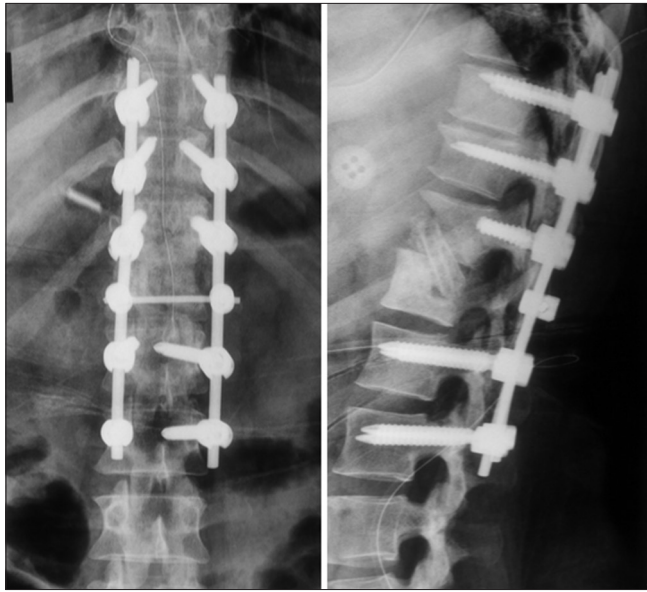
## Results

Cost quotations from the three most commonly used implant companies at our tertiary care center were taken, and the average cost for both the instrumentation methods was determined [Table 1] (1 US dollar = 71.62 Indian rupees as per current exchange rates). In the group in which the Hartshill loop rectangle and sublaminar wire fixation was used, the most commonly fused segments were 6, while the pedicle screw rod system group had four levels fused most commonly. Hence, the cost was calculated considering these many fusion levels. The average cost of Hartshill rectangle and sublaminar wire construct is 2500 Indian rupees, whereas that for a pedicle screw rod construct is 9300 Indian rupees.



**Figure 1:** Postoperative anteroposterior and lateral X-ray of a patient in Group A (Hartshill loop rectangle and sublaminar wire)

All patients underwent a minimum follow-up of 18 months, with a mean follow-up of  $61.23 \pm 24.57$  months (range, 18–156 months). Out of 186 patients, 100 were in Group A (Hartshill + sublaminar wire) and 86 were included in Group B (pedicle screw rod). The results are shown in Table 2. During the presentation, the mean value of preoperative kyphosis was  $25.02^\circ \pm 8.79^\circ$  (range,  $9^\circ$ – $45^\circ$ ) in Group A and  $26.01 \pm 9.16$  (range,  $10^\circ$ – $48^\circ$ ) in Group B. The average number of vertebral bodies involved was  $2.07 \pm 0.57$  (range, 2–4) in Group A and  $2.78 \pm 0.11$  (range, 2–4) in Group B. The mean immediate postoperative K angle was  $10.35^\circ \pm 4.96^\circ$  (range,  $1^\circ$ – $21^\circ$ ) in Group A and



**Figure 2:** Postoperative anteroposterior and lateral X-ray of a patient in Group B (Pedicle screw and rod)

| <b>Table 1: Cost of implant (all values in Indian rupees)</b> |                  |                  |
|---|------------------|------------------|
|   | <b>2000-2010</b> | <b>2011-2016</b> |
| 1 sublaminar wire   | 70               | 125              |
| 1 Hartshill loop rectangle                                    | 750              | 1000             |
| Cost (6 level fixation)                                       | 1590             | 2500             |
| 1 pedicular screw   | 600              | 850              |
| 1 rod   | 300              | 500              |
| 1 CLC   | 900              | 1000             |
| 8 screw and rod construct                                     | 6300             | 8800             |
| CNS – Crosslink connector                                     |                  |                  |

$11.77 \pm 3.56$  (range  $3^\circ$ – $23^\circ$ ) in Group B. Improvements in K angle were statistically significant ( $P < 0.001$ ) in both the groups. Pain improved from an average VAS score of  $7.02 \pm 0.97$  (range, 5–9) preoperatively to  $1.27 \pm 0.59$  (range, 1–3) at the final follow-up in Group A and  $7.66 \pm 1.27$  (range, 4–9) preoperatively to  $1.67 \pm 0.77$  (range, 1–4) at final follow-up in Group B. Improvements were statistically significant ( $P < 0.01$ ) in both the groups.

We had two cases of implant failure in Group A and two in Group B. There were four wound-related complications in Group A, out of which two healed by cleaning and dressing while two required secondary suturing. One patient in Group B had infection of a collected hematoma which needed a wound wash. One patient in Group A had buckling of graft [Figure 3] which consolidated in mild kyphosis and was managed conservatively by mobilization with TLSO.

In Group A [Table 3], 9 patients did not have any neurological deficit preoperatively; their neurological status was unchanged postoperatively. All 7 patients with Frankel Grade D recovered completely. Out of 40 patients with Frankel Grade C, 32 patients recovered fully and 8 patients recovered to Grade D. Out of 44 patients with Frankel Grades A and B, 28 patients recovered completely, 15 patients recovered to Grade D, and 1 patient remained paraplegic.

In Group B [Table 4], 6 patients did not have any preoperative neurological deficit; their neurological status was unchanged postoperatively. All 10 patients with Frankel Grade D recovered completely. Out of 40 patients with Frankel Grade C, 28 patients recovered fully and 12 patients recovered to Grade D. Out of 30 patients with Frankel Grades A and B, 19 patients recovered completely and 11 patients recovered to Grade D. Improvements were statistically significant ( $P < 0.01$ ). Fusion was achieved in all cases.

We had 16 cases of Multidrug resistance (MDR) TB in our series. As TB is a medical disease, the surgical protocols did not change depending on the MDR status. However, these patients were given appropriate AKT as per the drug sensitivity for a longer period (2 years).

| <b>Table 2: Results of the two groups of patients</b>                              |  |
|--|--|
| <b>Group A - Hartshill loop rectangle and sublaminar wire (total 100 patients)</b> | <b>Group B - Pedicle screw and rod (total 86 patients)</b> |
| Implant failure - 2 patients   | Implant failure - 2  |
| Breakage of wire distally: Converted to hybrid fixation                            | One required revision                                      |
| One pediatric patient had proximal wire cut out at 1 year: Implant removed         | One required implant removal                               |
| Wound related complications - 4 patients   | Wound complication - 1 patient                             |
| Healed with daily cleaning and dressing: 2   | Infection of collected hematoma. Wound wash given          |
| Secondary suturing required: 2   |  |
| Buckling Graft - 1 patient. Consolidated in mild kyphosis [Figure 3]               |  |



**Figure 3: Buckling of graft with consolidation in mild kyphosis**

**Table 3: Neurological status of patients operated by Hartshill loop rectangle and sublaminar wire**

| Preoperative Frankel stage (number of patients) | Postoperative Frankel stage (number of patients) |
|---|--|
| A (20)  | E (10), D (9), A (1)                             |
| B (24)  | E (18), D (6)                                    |
| C (40)  | E (32) D (8)                                     |
| D (7)   | E (7)  |
| E (9)   | E (9)  |

**Table 4: Neurological status of patients operated by pedicle screw and rod**

| Preoperative Frankel stage (number of patients) | Postoperative Frankel stage (number of patients) |
|---|--|
| A (18)  | E (11), D (7)                                    |
| B (12)  | E (8), D (4)                                     |
| C (40)  | E (28), D (12)                                   |
| D (10)  | E (10)   |
| E (6)   | E (6)  |

## Discussion

TB is among the most ancient diseases known to humankind. It is one of the top 10 infections causing mortality worldwide and is the number one infectious cause of mortality in HIV-infected patients (estimated 1.3 million mortalities due to TB among HIV-negative people and 3 lakh deaths among HIV-positive people). WHO, which considers TB as a pandemic, has created the “STOP TB” strategy<sup>[11]</sup> to end TB infection by the year 2030 and to eliminate TB by the year 2050. India with a population of 1.32 billion is a significant contributor to the burden of TB globally. As of 2017, India contributes (27%) 92.79 million TB globally and 25% of the global multidrug resistance (MDR) TB. There has been a rapid rise of

MDR TB cases among the Indian population. Three countries accounted for almost 50% of the world's cases of MDR TB: India (24%), China (13%), and the Russian Federation (10%).<sup>[12-14]</sup>

TB in India is further compounded by socioeconomic issues. 21.9% of the Indian population is below poverty line.<sup>[15]</sup> Furthermore, India has 37% of the world's illiterate adult population.<sup>[16]</sup> This subset of population living in urban slums is especially susceptible to TB.

Spinal TB is essentially a medical disease, and ATT forms the mainstay of treatment. In many patients in the absence of neurologic deficit, instability, and deformity, only ATT has been shown to be effective even in patients with a paravertebral abscess. General guidelines are to prove the diagnosis by biopsy and to start ATT as per the drug sensitivity report. Early pharmacological treatment by combination chemotherapy with appropriate drugs for an adequate duration can prevent the severe complications associated with spinal TB. A combination of four drugs (rifampicin, isoniazid, ethambutol, and pyrazinamide) for 2 months followed by combination of three drugs (rifampicin, isoniazid, and pyrazinamide) for a total period of 18 months is the ATT protocol used at our institute. Short-course chemotherapy regimens have been demonstrated to have excellent results except in patients younger than 15 years with an initial angle of kyphosis of more than 30° and whose kyphosis increases substantially.

The surgical indications have not changed significantly since Tuli proposed the “middle-path regimen” in 1975.<sup>[9]</sup> This included four main criteria: (I) absence of neurological recovery in spite of a fair trial of conservative therapy for 3 weeks, (II) onset of neurological complications during the conservative therapy, (III) patient with prevertebral cervical abscess leading to difficulty in deglutition and respiration, and (IV) advanced neurological involvement (flaccid paralysis, severe flexor spasm, and bowel-bladder involvement). At our institute, we also operated on pediatric patients with 2 or more “spine at risk” signs and in cases with unabated destruction at junctional areas.

Oga *et al.* observed no persistent or recurrent infection after surgery in patients with spinal TB treated with posterior spinal instrumentation.<sup>[17]</sup> The adherence property of *Mycobacterium tuberculosis* to stainless steel was evaluated experimentally. Few mycobacteria adhere to the stainless steel, whereas *Staphylococcus* heavily colonizes on stainless steel. Pyogenic organisms form a thick biofilm, whereas mycobacteria show a scanty biofilm. Hence, the use of implant in the presence of TB infection is theoretically safe. Potential advantages of spinal instrumentation include correction of deformity, wider resection of unhealthy bone without fear of instability and addressing the problem of instability when present, increased rate of fusion, especially multilevel spinal fusion, and early mobilization.

Here, we compared two methods of fixation. The use of pedicle screws is the most popular spinal instrumentation method today.<sup>[18,19]</sup> The advantage of pedicle screws is its capability to hold all the three columns of the spine, whereas Hartshill loop rectangle and sublaminar wire fixation wire gets a purchase over the posterior column structures alone. However, when combined with meticulous neural decompression and skillful preparation of osteogenic bed with autologous strut grafting and additional onlay grafting, it gives overall adequate stabilization of the column with results comparable with those of pedicle screws, as shown in this study. Our study showed that both the fixation methods had comparable clinical as well as radiological outcomes. The Hartshill loop rectangle and sublaminar wire fixation was much more cost-effective.

This study has limitations of its retrospective nature and experience at a single center. A prospective multicentric study with a larger sample size will further validate our findings.

## Conclusion

Hartshill loop rectangle and sublaminar wire fixation gets purchase over the posterior column structures alone when compared to pedicle screws which have a 3-column hold. However, when combined with meticulous neural decompression and skillful preparation of osteogenic bed with autologous strut grafting and additional onlay grafting, it gives overall adequate stabilization of the column with functional outcome comparable to pedicular screw and rod fixation with additional benefit of cost-effectiveness. Although Hartshill loop rectangle and sublaminar wire fixation is less commonly used now, it has a special place in the management of TB, especially in a resource-poor setting like some countries of Asia. Hartshill loop rectangle and sublaminar wire has a special place as it gives comparable results in terms of radiological and neurological outcome at a lesser cost. Furthermore, knowledge of this technique enables us to do hybrid fixation as a salvage procedure.

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## Conflicts of interest

There are no conflicts of interest.

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