Cost-effectiveness analysis of the Russian treatment scheme for tuberculosis versus short-course chemotherapy: results from Tomsk, Siberia


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of World Health Organisation (WHO)-recommended short-course chemotherapy (SCC), consisting of a standardised 6-month regime, for tuberculosis (TB) patients. This intervention was compared with the individualised Russian regimen, which relied on individualised antibiotic regimens, often with adjunct therapies and surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised new WHO Category I TB patients, who were older than 18 years of age and who were living in Tomsk Oblast, Western Siberia. The socioeconomic status and gender of Oblast's TB patients of all WHO categories in 1996 (n=607) were as follows:

79% were male and 21% female, with a mean age of 40 years (standard deviation, SD=14) for the males and 36 years (SD=11.5) for the females;

28% were employed, 42% were unemployed, 24% were pensioners and 8% were students.

Setting
The practice setting was secondary care. The economic study was carried out in Tomsk Oblast, Western Siberia, Russia.

Dates to which data relate
The effectiveness measures were derived from a trial conducted between March 1995 and June 1996. The economic analysis used 1997 prices.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
No study sample size seems to have been determined in the planning phase of the study. In addition, no power calculations were performed retrospectively. A total of 646 new TB patients were included in the study. They were systematically allocated to traditional Russian TB treatments (356 patients, of which 155 were smear-positive) or WHO SCC (290 patients, of which 155 were smear-positive). Only the treatment outcomes of the smear-positive TB patients were considered in this study. Thus, there were 155 patients in each group.

**Study design**

The study was a randomised controlled trial (RCT), which was carried out in the two largest TB diagnostic and treatment centres in Tomsk Oblast, Western Siberia. The authors did not state the method used to allocate the patients to the groups. The duration of follow-up would appear to have been 6 months for both groups. Of the 155 patients in the Russian method group, 17 (11%) died, 16 (10%) defaulted and 2 (1%) were transferred out. Of the 155 patients in the SCC group, 13 (8%) died, 21 (14%) defaulted and 5 (3%) were transferred out.

**Analysis of effectiveness**

The analysis of the clinical study was conducted on the basis of intention to treat only. The primary health outcome was the observed cure rate. For both treatment regimens, cure was defined by smear conversion and was determined by microscopic examination of sputum. The observed cure rate was defined by the WHO and the IUATLD as patients who were smear-negative at, or one month prior to, the completion of treatment and on at least one prior occasion. For the Russian method group, information on frequency of surgery, adjunct therapies and TB drug use was obtained from the records of 104 patients for whom complete data were available.

**Effectiveness results**

The observed cure rates of this trial were 56% (86 patients) for the individual Russian treatment and 54% (84 patients) for SCC.

**Clinical conclusions**

Both treatment regimens revealed similar observed cure rates, with the Russian method having an observed cure rate 2% higher than SCC. It is unclear whether these differences were statistically significant, as no statistical tests of significance were performed.

**Measure of benefits used in the economic analysis**

The measures of benefits included in the analysis were the number of TB cases cured and the number of life-years saved (LYS).

**Direct costs**

The resources used and the costs were reported separately. The direct costs included in the analysis were those of the health care provider and the patient. For the health service provider, these covered staff, supplies, overheads, hospitalisation and drugs. For the patient, these were for the time and travel costs associated with treatment.

All the costs to the health service provider were derived from the hospital, not taking the expenditures of the dispensary and polyclinic into account. The monthly salaries of staff were taken as an average cost per staffing group, and included hospital expenditure on housing. The costing of the adjunct therapies and surgery was carried out using observation to quantify the time spent by staff, the number of staff involved per procedure and consumables used. The costs of anti-TB drugs were obtained from international catalogue prices, whilst the costs of drugs used for adjunct therapies were derived from Russian medical company catalogues. Laboratory costs were not included. The patient costs were obtained through interviews conducted on a random selection of 98 patients, using a structured questionnaire.

The capital costs were annualised using a discount rate of 3%, with an expected useful life of 30 and 10 years being assumed for the hospital building and the therapeutic devices, respectively. All the costs for the TB hospital were based
on expenditure during the 1996 financial year and were adjusted for inflation to 1997 values. Discounting was irrelevant since the costs were incurred in less than one year, and was not performed.

**Statistical analysis of costs**
The costs and resource use were treated as point estimates (i.e. the data were deterministic).

**Indirect Costs**
The indirect costs included in the analysis were expenditure on transport during treatment, and the loss of income due to the inability to return to work during and after treatment. The costs incurred by the patients and their families were ascertained through interviews conducted on a random selection of 98 patients, using a structured questionnaire. Of the 98 patients interviewed, 76 were men and 22 were women. The costs were calculated in 1997 prices. Discounting was irrelevant since the costs were incurred in less than one year, and was not performed.

**Currency**
US dollars ($). Currency conversions were performed. The US$-Russian Rouble exchange rate of 1997 was 1 US$ = Roubles 5,800.

**Sensitivity analysis**
A sensitivity analysis was carried out. It was assumed that employed patients receiving SCC were hospitalised for 2 weeks or 2 months, and resumed work thereafter without loss of income, and that every patient paid for transport.

**Estimated benefits used in the economic analysis**
The estimated benefits used in the economic analysis were based on a cure rate of 56% for the Russian regimen and 54% for SCC. Taking into account the age distribution of TB patients, the number of LYS per cure was 25.6 for males and 34.9 for females. Taking into account the proportion of males and females for all new cases of TB in Tomsk Oblast in 1996, the number of LYS per cured TB case was 28.3.

**Cost results**
The cost to society of treating TB patients was $1,584 when using the traditional Russian method and $1,302 when using SCC.

**Synthesis of costs and benefits**
The costs and benefits were combined in two ways. First, as the cost per case cured, and second, as the cost per LYS. The authors did not undertake an incremental analysis. The cost per cure was $2,295 when using the Russian method and $1,901 when using the SCC. The cost per LYS was $125 for patients undergoing the individualised Russian regimen and $103 for those undergoing SCC.

From the sensitivity analysis, the cost per cure varied from $556 for SCC with 2 weeks' hospitalisation to $1,457 with 2 months' hospitalisation. Hence, the cost per LYS hence varied from $30 to $79.

**Authors' conclusions**
From an economic point of view, short-course chemotherapy (SCC) in tandem with 2 weeks' or 2 months' hospitalisation and an absence of surgery was clearly the optimal strategy for treatment in the Tomsk region. This is because both the household and provider costs were substantially lower than with the individualised Russian treatment scheme, and would only require a sixth of the current TB control budget.
CRD COMMENTARY - Selection of comparators
The choice of the Russian individualised method as the comparator was justified on the grounds that it represented current practice in the study setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a RCT. This was appropriate for the study question, as well-conducted RCTs are the ‘gold’ standard study design when comparing different health interventions. However, even though the analysis was based on a RCT and the outcomes were analysed on an intention to treat basis, the internal validity of the study would have been enhanced had the authors reported how the participants were randomised to the study groups. Further, the authors failed to demonstrate whether the two study groups were comparable at analysis, and no characteristics were given for each sample of patients. The authors failed to perform appropriate statistical tests of significance to show whether any differences in effectiveness were statistically significant. They also pointed out that the complete absence of any standardisation in the treatment and hospitalisation patterns might have biased their findings.

Validity of estimate of measure of benefit
The number of cases cured was obtained directly from the effectiveness analysis. However, the source used to establish the number of LYS per cured TB case (28.3 years) was not stated. The authors only stated that the age distribution of TB patients was taken into consideration. The use of LYS was justified, as the important outcome was life expectancy rather than quality of life.

Validity of estimate of costs
All the categories of cost relevant to the societal perspective adopted were included in the analysis. Some relevant cost items within these categories were omitted from the analysis. The laboratory costs were not included, as time limitations and non-standardised use did not allow the numerous tests to be costed. Also excluded were the follow-up of treated patients and the provision of monotherapy twice annually for these persons to prevent relapse. However, it would appear that such omissions are unlikely to have affected the authors’ conclusions. The costs and the quantities were reported separately, which will enhance the generalisability to other settings. Further, the break-up of the costs and how they were calculated were reported extensively.

Resource use was obtained from patients who participated in the trial and for whom complete data were available. No statistical analysis of the quantities was performed. The unit costs were mainly determined from the authors' setting, with no statistical analysis of the prices being performed. However, the authors did perform a sensitivity analysis to assess the impact that different lengths of hospitalisation in the SCC group would have on the cost-effectiveness results. The authors performed appropriate currency conversions. Discounting was unnecessary since all the costs were incurred in less than two years. The price year was reported, which will aid any possible reflation exercises.

Other issues
The authors made appropriate comparisons of their findings with another cost-effectiveness study comparing SCC with the Russian treatment approach. The study also demonstrated that the cost per case cured using SCC with up to 3 months’ hospitalisation was substantially lower than the cost per case cured using the individualised Russian treatment. The issue of generalisability to other settings was addressed, with the authors questioning if their findings could be extrapolated to other regions of the Russian Federation. The authors do not appear to have presented their results selectively. Their conclusions reflected the scope of the analysis, as all the conclusions were based on the Tomsk Oblast patients and were not generalised to the whole of Russia.

It would have been desirable for the authors to have calculated an incremental cost-effectiveness ratio comparing SCC with the Russian method, with the reduced costs of SCC being compared with the reduced effectiveness of SCC, in order to provide an appropriate measure for expressing the final results. The authors reported a further limitation to their study. They assumed that employed patients who lost their jobs during treatment would find employment 6 months after treatment. Due to the economic situation in Russia, the authors viewed this as very optimistic.
Implications of the study
The authors viewed the shift to SCC as warranted due to the lower indirect costs for the individual. However, due to the numerous beds available in the country for the treatment of TB patients, and the consequent employment opportunities these provide, a sudden shift is unrealistic. The authors also recommended that TB services and social services should collaborate more closely. In addition, that social services should also bear the transport costs and assist patients by providing an income during the duration of treatment, which would most likely improve the patients’ compliance with the treatment.

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