Lower extremity amputation prevention in Singapore: economic analysis of results

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ABSTRACT

Introduction: The aim of the study was to determine the cost-effectiveness of the Lower Extremity Amputation Prevention (LEAP) strategy in comparison to standard clinical practice for treating patients with critical limb ischaemia (CLI).

Methods: A retrospective cost-effectiveness analysis of the LEAP programme relative to pre-LEAP practice was performed from the perspective of Singapore hospitals. The cost incorporated in the analysis included direct medical costs incurred during the admission. Outcomes included the number of amputations, number of deaths and length of hospital stay after the initial treatment.

Results: During the study period, the LEAP group had a lower amputation rate (29 percent versus 76 percent, p-value is 0.00001), lower related death rate (one percent versus 19 percent, p-value is 0.00001) and fewer in-hospital days per patient (17.8 days versus 23.16 days, p-value is 0.048) as compared to the standard clinical practice group. The implementation of the LEAP strategy generated cost savings of S$2,566 per patient during admission when compared with the pre-LEAP approach. The results were robust to variations in input parameters.

Conclusion: The LEAP strategy dominated standard practice in the management of patients with diabetes mellitus and CLI. The implementation of the LEAP strategy significantly improved patient outcomes and reduced hospital costs.

Keywords: cost-effectiveness, critical limb ischaemia, hospital cost savings, limb salvage, percutaneous angioplasty

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INTRODUCTION

Diabetes mellitus is one of the most significant and prevalent metabolic diseases in Singapore. The 2004 Singapore National Health Survey reported that 8.2% of the population were affected by the disease. In 2007, diabetes mellitus was the seventh most common cause of death in Singapore, accounting for 3.6% of the annual total mortality.[1] Critical limb ischaemia (CLI) is a chronic complication among some patients with diabetes mellitus, which often leads to lower extremity amputation (LEA) and subsequently increases the risk of mortality.[2-4] Persons with diabetes mellitus are five times more likely to develop CLI than those without diabetes mellitus.[5]

The importance and advantage of a multidisciplinary team in treating patients with CLI has been highlighted and encouraged in the literature.[6-8] The Lower Extremity Amputation Prevention (LEAP) programme was implemented in 2001 by the Vascular Unit of the Department of Surgery at Tan Tock Seng Hospital, Singapore. The aim of the LEAP programme was to enhance limb salvage for patients with CLI. The programme was funded for four years from 2001 to 2005. Clinical data relating to patient outcomes in the LEAP programme was collected during the study period. However, there was limited information concerning the economic costs associated with the programme relative to standard practice. The aim of the economic analysis was to determine the cost-effectiveness of the LEAP strategy as opposed to the standard clinical practice for treating patients with diabetes mellitus who develop CLI.

METHODS

LEAP was a multidisciplinary management strategy designed to treat patients with diabetes mellitus and CLI. The general treatment goal was to achieve primary healing of foot lesions in order to avoid unnecessary amputation and related death. A total of 388 patients with CLI who were admitted to the Vascular Unit, Tan Tock Seng Hospital were enrolled in LEAP during the first admission period in 2001. Patients were followed up

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Table I. Cost inputs used in the analysis.

Variable	Unit	Full Price (S$)	Source*
Angiogram	Per angiogram	1,650	Radiology department
HBOT	Per course (20 sessions)	5,200	HBOT department
IPC	Per session	0	Assumption
Thrombolysis	Per patient	5,000	Radiology department
Angioplasty	Per patient	1,850	Radiology department
Bypass	Per operation	11,380	Surgical department
Medical management	Per patient	4,563	Medical billing records
Ray's amputation	Per operation	4,010	Surgical department
BKA	Per operation	7,150	Surgical department
AKA	Per operation	7,150	Surgical department
Hospital stay	Per hospital day	338	Inpatient charges and daily treatment fee

* Source: Tan Tock Seng Hospital
HBOT: hyperbaric oxygen therapy; IPC: intermittent pneumatic compression; BKA: below knee amputation; AKA: above knee amputation

until the final outcome (amputation or death) during their inpatient episode, and those who were discharged were followed up for four years.

No previous randomised studies have compared LEAP with standard practice. In order to compare patient outcomes associated with the implementation of LEAP relative to conventional practice (pre-LEAP), the data of 155 patients with CLI who were referred to the Vascular Unit before the implementation of LEAP was obtained. Historical data for this patient group was only available for the patients' initial period of hospitalisation in the year 2000. For consistency, the analysis of costs and health benefits for the LEAP and pre-LEAP cohorts focused on the inpatient period only.

Diabetes mellitus was less prevalent in the LEAP study compared with the pre-LEAP period (82.7% vs. 92.9%, p = 0.003). Research has convincingly demonstrated that diabetes mellitus is the leading cause of LEA; the rate of LEA among diabetic patients is 15 times higher than that in patients without diabetes mellitus.[9-11] Furthermore, patients with diabetes mellitus have an increased risk of death compared to those who do not have diabetes mellitus.[4] Thus, a comparison of outcomes (rates of amputation and related death) for all patients in both groups could be biased toward the LEAP group due to the lower proportion of patients with diabetes mellitus in that group. For this reason, data analysis was performed only for patients with both diabetes mellitus and CLI.

All patients enrolled in the LEAP study underwent multidisciplinary management to ensure that a comprehensive medical approach was applied, as well as to eliminate strategic differences between individual physicians and surgeons. Amputation was performed only if the management strategy failed. The vascular statuses of patients were established using duplex ultrasonography and clinical examination. Patients were stratified into treatment groups based on their risk of foot complications, and underwent angioplasty, bypass or other therapeutic procedures based on clinical management protocols.

During the pre-LEAP period, there was no established systematic approach to clinically manage this patient group. They were managed by an orthopaedic team and rarely referred to the vascular team. The usual treatment involved wound debridement, antibiotics and monitoring of blood sugar level. Amputation was usually performed when wounds failed to heal. Case report forms that documented the details of therapeutic procedures and clinical outcomes during hospitalisation for both patient groups were analysed after completion of the LEAP study. The rate of amputation, rate of death and the mean length of inpatient stay were considered as outcome measures to assess the effectiveness of the LEAP approach in the economic study. Variables relating to therapeutic management and clinical outcomes were presented either as a percentage (number of events/total number of patients) or mean with standard deviation (SD). Informed consent was waived for the clinical part of the study.

Chi-square test was used to compare the use of different therapeutic management strategies and amputation incidences between the two groups. A one-tailed *t*-test was performed to compare the number of deaths and the lengths of in-hospital stay between the two groups. A p-value < 0.05 was considered to be statistically significant. All statistical analyses were conducted using Microsoft Excel 2003® (Redmond, WA, USA). The total costs of the LEAP and pre-LEAP approaches were determined on the basis of therapeutic procedures, length

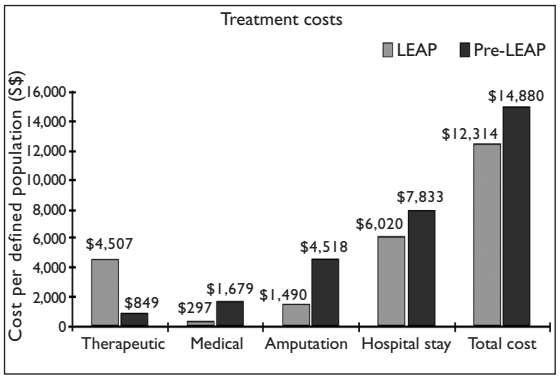

Fig. 1 Bar chart shows the total cost comparison for LEAP and pre-LEAP.

of hospitalisation and the surgical procedures performed during the admission period. Outpatient care and rehabilitation costs were not reported, and were therefore not included in the analysis. Cost data is presented in Table I.

Charges for the same treatment or surgery vary considerably between government-subsidised and non-subsidised patients in Singapore hospitals. Data from the Tan Tock Seng Hospital that was analysed for this study related to non-subsidised patients, also known as 'full price' admissions. Fees paid by non-subsidised patients are more indicative of actual hospital costs and were therefore considered more appropriate. All cost calculations were conducted using 2008 Singapore dollars on a per patient basis. The estimates of therapeutic management costs included those directly related to the use of specific patient resources. These costs were based on an official price list of Tan Tock Seng Hospital fees, with the addition of average consumable costs incurred for specific procedures. For example, the listed fee per angiogram procedure was $900, the cost of consumables per angioplasty was estimated to be $750 and the total cost per angiogram was estimated to be $1,650 (Table I).

The average cost of consumables for therapeutic and surgical procedures was also obtained from Tan Tock Seng Hospital. The cost of pneumatic pressure facilities was not charged to inpatients; this cost was therefore assumed to be negligible and excluded from the economic analysis. Patients who did not receive therapeutic management or who underwent amputation received optimal medical treatment on the basis of their condition. A total of 71 patients in both groups received medical treatment (18 in LEAP and 53 in pre-LEAP). A record of medical management cost data was available for 28 patients who received medical treatment under either LEAP or pre- LEAP. Medical treatment costs were estimated on the basis of actual resource use. These costs varied between patients due to differences in resource requirements associated with their conditions. The average medical treatment cost per patient was used to represent the cost of resource use for medical treatment in both groups. The average medical treatment cost per patient was derived in 2000 Singapore dollars and inflated to 2008 Singapore dollars using the Singapore health expenditure index (Singapore Department of Statistics, Singapore 2007 and 2008).

The average cost of Ray's procedure, below knee amputation (BKA) and above knee amputation (AKA) included the surgical procedure, consumables, surgeons' fees and post-amputation care during admission (Table I). The cost of length of hospital stay in the analysis was defined as the use of the room and associated routine services provided during admission. The cost per hospital day, obtained from Tan Tock Seng Hospital, was $338 ($272 hospital day fee + $66 fixed daily treatment fee). Indirect costs, in terms of lost productivity and missed working days, were not included in the analysis for two reasons. Firstly, most patients in the two groups were above the Singapore retirement age of 62 years (73% in the LEAP and 71% in the pre-LEAP studies, respectively). Secondly, it was challenging to differentiate the extent to which productivity costs were related to either patients' primary conditions, amputations or other underlying diseases.

A retrospective cost-effectiveness analysis of LEAP relative to pre-LEAP for the management of patients with diabetes mellitus and CLI was performed from the perspective of a Singapore hospital. Costs incorporated in the analysis included direct medical costs incurred during the admission only. Outcomes included the rate of amputations, the rate of death and the mean length of hospital stay after the initial treatment. Three cost-effectiveness outcomes were evaluated and expressed as incremental cost-effectiveness ratios (ICERs). 'Incremental' refers to the difference between interventions, and the incremental change in costs of the interventions is divided by the incremental change in benefits. The ICER is denoted as:

$$ICER = \frac{Cost_{LEAP} - Cost_{Pre\text{-}LEAP}}{Effect_{LEAP} - Effect_{Pre\text{-}LEAP}}$$

The ICER highlights the importance of the margin (the additional cost of achieving an additional unit of benefit) in the economic analysis. The cost-effectiveness outcomes were the incremental cost avoided per amputation (LEAP vs. pre-LEAP), per death (LEAP vs. pre-LEAP) and per hospital day (LEAP vs. pre-LEAP). ICERs were not calculated if one treatment strategy dominated another (less expensive and more effective).

Table II. Baseline characteristics of patients with diabetes mellitus who developed critical limb ischaemia.

Variable	No. of patients (%)		p-value
	LEAP (n = 277)	Pre-LEAP (n = 144)	
Mean age ± SD (yrs)	67.2 ± 15.2	68.5 ± 12.5	0.452
Gender			
Male	142 (51.3)	71 (49.3)	0.703
Female	135 (48.7)	73 (50.7)	
Limb site			
Left	144 (52.0)	69 (47.9)	0.418
Right	114 (41.2)	58 (40.3)	
Both	19 (6.9)	17 (11.8)	
Risk factor			
Hypertension	191 (69.0)	90 (62.5)	0.183
Hyperlipidaemia	108 (39.0)	31 (21.5)	0.0003
Ischaemic heart disease	114 (41.1)	60 (41.7)	0.920

LEAP: Lower Extremity Amputation Prevention; SD: standard deviation

Table III. Summary of therapeutic management strategies

Variable	No. of patients (%)		
	LEAP	Pre-LEAP	Difference*
Angiogram	14 (5.1)	20 (13.9)	−6 (−8.8)
HBOT	45 (16.3)	1 (0.7)	44 (15.6)
IPC	6 (4.2)	1 (0.7)	5 (3.5)
Thrombolysis	7 (2.5)	1 (0.7)	6 (1.8)
Angioplasty	234 (84.9)	12 (8.3)	222 (76.2)
Bypass	46 (16.6)	5 (3.5)	41 (13.2)
Overall	259 (93.5)	91 (63.2)	168 (30.3)

*The difference is derived from LEAP minus pre-LEAP.
Note: Patients who did not receive therapeutic management or who underwent amputation received optimal medical treatment.
LEAP: Lower Extremity Amputation Prevention; HBOT: hyperbaric oxygen therapy; IPC: intermittent pneumatic compression

Several one-way sensitivity analyses were conducted to determine whether these results were sensitive to cost or effectiveness variables. All data and calculations were provided using Microsoft Excel 2003®.

RESULTS

The demographics, baseline comorbidities and presenting conditions of patients enrolled in the LEAP and pre-LEAP periods are outlined in Table II. The analysis included a total of 277 patients with diabetes mellitus and CLI in the LEAP group and 144 in the pre-LEAP group. Baseline demographic and comorbidity characteristics of the patients were well-matched in both groups. The only significant difference in reported baseline risk factors was hyperlipidaemia, which was more prevalent among patients in the LEAP group (38.99% vs. 21.53%, p = 0.003). Hyperlipidaemia is frequently associated with diabetes mellitus and contributes significantly to the incidence of coronary heart disease.[12] An increased risk of coronary heart disease amplifies the risk of mortality for diabetes mellitus patients. Given that deaths in the study were associated with amputation in patients with diabetes mellitus and CLI, it is unlikely that the prevalence of hyperlipidaemia affected the outcomes.

A higher proportion of patients in LEAP underwent therapeutic management. The major therapeutic management strategies are presented in Table III. During admission, 94% of patients in LEAP underwent at least one therapeutic management strategy, as compared to only 63% of patients in the pre-LEAP group. The implementation of LEAP resulted in significant reductions in the rate of amputation, mortality and length of hospital stay. The outcome results for both groups are presented in Table IV. During admission, the incidence of amputation decreased significantly by 47%, from 76% (pre-LEAP) to 29% (LEAP). Moreover, only 1% of patients died during admission in the LEAP group compared with 19% in the pre-LEAP group. These differences were statistically significant. The average length of hospital stay was significantly reduced by five days, from 23 days to 18 days.

The inhospital costs per patient for both groups are presented in Table I. The costs of therapeutic management were $4,507 and $849 per patient for the LEAP and pre-LEAP groups, respectively, and the costs of medical management were $297 and $1,679 per patient for the LEAP and pre-LEAP groups, respectively. The overall cost during a patient's initial admission was higher by $2,275 under LEAP compared with the pre-LEAP group. This incremental cost was entirely driven by the increased use of therapeutic management in LEAP, in particular, angioplasty ($1,563 in LEAP vs. $154 in pre-LEAP, p = 0.0001) and bypass ($1,890 in LEAP vs. $395 in pre-LEAP, p = 0.0001).

The implementation of LEAP was associated with substantial reductions in amputation rates and length of hospital stay, as well as significant reductions in related healthcare costs. The mean total cost per patient for amputation and hospital stay was lower by $4,841 in the LEAP group compared with the pre-LEAP group. Therefore, although the initial management cost for LEAP was higher due to the increased therapeutic management cost, this was fully offset by cost savings to the hospital associated with preventing amputations. Under LEAP, there was a net cost saving of $2,566 per

Table IV. Treatment outcome comparison for LEAP and pre-LEAP.

Outcome	% Incidence		Difference	p-value
	LEAP	Pre-LEAP		
Overall amputation rate	29.2	75.7	46.5	0.00001
Ray's amputation	19.1	28.5	9.3	0.00001
BKA	8.7	34.0	25.4	0.00001
AKA	1.4	13.2	11.8	0.00001
Mortality rate	0.4	13.2	12.8	0.00001
Inhospital days	17.8	23.2	5.4	0.048

LEAP: Lower Extremity Amputation Prevention; BKA: below knee amputation; AKA: above knee amputation

Table V. Sensitivity analysis results.

Scenario	Cost (S$)		
	LEAP	Pre-LEAP	Difference
Base case	12,314	14,880	−2,566
Amputation rate in LEAP			
Lower 95% CI limit: 23.9%	12,041	14,880	−2,838
Upper 95% CI limit: 34.6%	12,587	14,880	−2,292
Amputation costs			
Increased 25%	12,686	16,009	−3,323
Decreased 25%	11,941	13,750	−1,809
Cost per hospital stay			
Increased 25%	13,819	16,838	−3,019
Decreased 25%	10,809	13,750	−2,113

LEAP: Lower Extremity Amputation Prevention; BKA: below knee amputation; AKA: above knee amputation

patient compared with the practice in the pre-LEAP setting. The LEAP strategy dominated standard practice, since it resulted in both cost saving and better patient outcomes. Thus, the additional benefits of LEAP did not come at an additional cost, and ICERs were not calculated.

Since some parameters in the model were either uncertain or subject to specific hospital treatment practice, their variability may have influenced the results. The impact of varying the input parameters was examined using several one-way sensitivity analyses (Table V). The overall amputation rate in LEAP varied between the 95% confidence interval (CI) limits (23.9%, 34.6%), maintaining the observed proportions of total amputations by type (Ray's, BKA or AKA). In other sensitivity analyses, the costs of amputation and hospital stay were increased or decreased by 25%. The sensitivity analyses indicated that the results were very sensitive to the rate of amputation, costs per amputation and cost per hospital bed day. A reduction in the amputation rate under LEAP led to lowered amputation costs and associated admission costs, suggesting greater cost savings compared with standard practice, and vice versa. This was anticipated, as the rate of amputation represents the key factor in the analysis, influencing the likelihood of avoiding a costly surgical procedure. In the area of cost input, the increase in amputation and hospital bed day costs resulted in increased differences in total costs in both groups, leading to greater cost savings under LEAP relative to pre-LEAP, and vice versa. This was expected, as length of hospital stay and amputation entail high costs, which are the major contributors to increased total costs. Overall, the implementation of LEAP was cost saving in all sensitivity analyses.

DISCUSSION

A retrospective economic evaluation of LEAP for limb salvage was carried out from the perspective of a Singapore hospital. The objective of this study was to evaluate the cost-effectiveness of implementing LEAP and to provide clinical decision makers with a better understanding of the implications in relation to healthcare costs, treatment strategies and outcomes for patients with diabetes mellitus who develop CLI. In this study, the implementation of LEAP, a strategy that provides a multidisciplinary approach for the clinical management of patients with diabetes mellitus with CLI, resulted in a 46.5% reduction in the amputation rate, 12.8% decrease in mortality and an average reduction of five hospital days per patient. Although the implementation costs for LEAP involved a higher therapeutic cost compared with the conventional (pre-LEAP) approach (primarily driven by higher usage of angioplasty [84.48% vs. 8.33%], and bypass [16.61% vs. 3.47%]), the analysis suggests that this cost is fully compensated by fewer amputations and inpatient days. The implementation of LEAP generated cost savings of $2,566 per patient during admission when compared with the pre-LEAP approach. The analysis was sensitive to the reduction in amputation rates under LEAP, cost per amputation and cost per bed day. On the whole, the implementation of LEAP generated cost savings for a range of plausible input parameter variations.

In light of the increasing demand for healthcare, it is important to consider both the total costs and cost-effectiveness of treatment options. The results of this study indicate the positive effects from optimising outcomes with limited financial resources for management of inpatients with diabetes mellitus and CLI in a Singapore hospital. The study finds LEAP to be cost saving compared with previous practice. This suggests that given a fixed budget, more patients with diabetes mellitus and CLI could be treated under LEAP, or additional resources could be made available for other groups of patients.

Indirect costs of lost productivity/salary were not included in the analysis, as more than 73% of patients were above the retirement age. However, patients who undergo amputation may require assistance from carers both during their inpatient episode and following discharge. The total indirect cost of carer time is expected to be lower under LEAP due to the lower rate of amputation. Therefore, excluding indirect costs from the analysis is likely to underestimate the true economic benefit of LEAP. Tan et al suggested that a multidisciplinary approach for treating patients with CLI in a Singapore hospital resulted in improved limb salvage. They reported a 29% amputation rate that resulted from a multidisciplinary approach applied for clinical management of 79 patients with CLI.[13] This rate was comparable with the findings observed in the LEAP group. However, the study did not compare the outcomes with a pre-study control; hence, the magnitude of improvement in limb salvage is unknown. Furthermore, an economic analysis was not performed; thus, it is unclear whether the cost savings associated with the limb salvage strategy would offset the overall costs involved in implementing the strategy described.

Other economic studies have indicated that a multidisciplinary approach was cost-effective for diabetic foot management. Horswell et al[14] compared the costs and effectiveness of a multidisciplinary approach with standard practice for management of diabetic foot over one year. The group undergoing a multidisciplinary strategy had fewer amputations, shorter length of hospitalisation and significantly fewer foot-related treatment charges (US$4,776 vs. US$9,402 per patient, $p = 0.014$), suggesting that the multidisciplinary approach was superior to standard practice.[14] Ragnarson-Tennvall et al[15] analysed the cost-effectiveness of an 'intensive prevention' programme in patients with diabetes mellitus who had varying risks of developing foot ulcers and amputation using a five-year Markov model simulation. Under the base case assumption of a 25% reduction in amputation, the multidisciplinary approach was found to promote cost savings of up to €969 for patients at high risk of foot ulcers and amputation, or be cost-effective (< €100,000/QALY) in all patient groups with a minimum of one risk factor.[15] It is, however, difficult to compare the results of these studies due to the differences in study designs, costing methods, healthcare systems, populations and analytical approaches.

The current study has some limitations. The economic analysis applied data from a non-randomised prospective study, and information for the comparator group was retrospectively collected from an earlier period. However, since the demographics and comorbidities at baseline for both groups were broadly equivalent after controlling for confounding effects of diabetes mellitus, the primary endpoints were well documented in claims data, and as both hospital admissions and procedures were routinely captured, it is suggested that these outcomes and the resulting costs analysis were accurate. Due to data limitations, this analysis considered costs accrued during the initial admission from the hospital perspective only. Cost-effective management of patients with diabetes mellitus should also focus on long-term costs. Patients who undergo lower limb amputations are at increased risk of further amputation and lifetime disability. Given the lower rate of amputation under LEAP, it is thus suggested that the implementation of LEAP would generate additional cost savings in the long run. Further investigation and patient follow-up is required to determine the long-term cost-effectiveness of LEAP.

In conclusion, amputation is a costly consequence for diabetic patients who develop CLI. The procedure requires prolonged hospitalisation and carries an increased risk of further amputation and death.[16] A key action to reduce healthcare management costs for patients with diabetes mellitus and CLI is to avoid amputation. The LEAP programme offers benefits for both patients and the healthcare system. It has successfully diminished the amputation rate, associated mortality and healthcare costs. LEAP is determined to be a cost-saving strategy as compared to the previous practice. Although therapeutic costs are higher, reductions in amputation rates and hospital days lead to lower total healthcare costs. The findings of this study provide additional support for decision makers to fund the LEAP approach in the hospital setting. Given the significant disease burden of LEA and the cost advantage associated with implementation of the LEAP approach, hospitals in the region should be encouraged to establish multidisciplinary teams and implement the LEAP strategy, keeping in mind that costs, prevalence and benefits from intervention might differ in the region. Integrating the LEAP approach into clinical practice would facilitate hospitals' provision of optimal management for patients with CLI, and subsequently, reduce amputation rates, mortality, average in-hospital length of stay and associated costs.

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