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The health economics of the treatment of long-bone non-unions

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Summary A review of the existing evidence on economic costs of treatment of long-bone fracture non-unions has retrieved 9 papers. Mostly the tibial shaft non-unions have been utilised as models for these economic analyses. Novel treatment strategies like BMP-7 grafting, Ilizarov ring external fixation or supplementary use of therapeutic ultrasound devices have been compared with standard methods of treatment focusing on direct and indirect costs and expenses.
A cost-identification query was conducted and revealed costs of £15,566, £17,200 and £16,330 for humeral, femoral, and tibial non-unions respectively on a "best-case scenario". The existing scientific evidence can only imply the extent of the economic burden of long-bone non-unions. Further systematic studies are needed to assess the direct medical, direct non-medical, indirect, and monetised quality of life and psychosocial costs of non-unions.

Introduction

Fracture non-unions represent a difficult challenge for the surgeon, the patient, and thus also to the health system and the social services supporting them. Their average treatment management requires large assets and long-lasting therapies with frequent unrewarding results. Overall long-bone fracture non-unions are rare, but they are also proportionate to high-energy trauma rates which are rising in our modern times.[1-3]

Conventionally, long-bone fracture non-unions have been treated with debridement of the non-union site and internal plate fixation, or over-reaming and intramedullary nailing (IMN), with or without the application of autogenous cancellous bone graft.[2] External fixation systems and especially Ilizarov circular frames lately have been added to the surgeon's armamentarium.[4] Grafting of the non-union site is based on the concept of providing biological stimuli enhancing healing rates.[5-8] Externally applied systems such as electrical stimulation[9,10], or low-intensity pulsed ultrasound[11,12] provide non-invasive alternatives, or supplementary treatments. Non-union treatment's end-point is defined as painless full weight-bearing (clinical union) and radiological evidence of bridging callus of three cortices in two planes (radiological union).[1] Supplementary investigational means like bone scintigraphy or moreover Computer Tomography (CT) are often used to monitor and document bone healing.

All these, as far as health economics are concerned, are some of the direct costs of treatment. A thorough economic analysis measures direct, indirect, and intangible costs.[13] It incorporates both the direct monetary costs, as

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Table 1
Description of economic costs necessary for a complete health economic analysis of non-unions

Direct costs		Indirect costs[18-20]	Intangible costs[21-23,20]
Medical[16,17]	Non-medical[16,17]		
• Surgical interventions (type and number of operations undergone). • Personnel costs. • Supplies costs (theatre equipment, implants, grafts, orthopaedic ancillary materials). • LOS (Ward-HDU-ICU). • Diagnostic investigations (haematological, microbiological and radiological). • Medications administered. • Outpatients attendances. • Physiotherapy	• Transportation of patients & of their families during the course of treatment. • Lodging of patients & of their families during the course of treatment.	• Lost productivity (lost wages or an imputed monetary value of time). • Lost earnings of the patient and the caring person. • Impairment Direct Payments. • Residential and Nursing care. • Insurance administration costs. • Legal costs.	• Quality of life[20] (associated with pain, suffering, and grief). • QALY.[22,23,20] • Psychosocial parameters.[21]

HDU, High Dependency Unit; ICU, Intensive Care Unit; LOS, Length of Stay; QALYs, monetised Quality-Adjusted Life Years.

well as the indirect costs associated with the duration of therapy, the final functional outcome and any disability payments of each patient.[14,15] A description of these different aspects of non-union costs is presented in Table 1.

The aim of this study is to review the existing evidence of the average economic cost of treatment of long-bone fracture non-unions, and also to provide clear guidelines as to which parameters an economic analysis of the treatment schemes for non-unions should incorporate.

Methods

Our effort to assess this subject was conducted in two parallel ways. Initially we have used MEDLINE for a standard literature search in order to collect the existing evidence of the economics of long-bone fracture non-unions. The keywords of "nonunion/s", "economics", "cost/s", "health economics", "long bone/s", "femur", "tibia", "humerus", "fractures" have been used in an OVID search engine query (http://gateway.uk.ovid.com), and as exclusion criteria we used languages other than English, case reports, case series referring to less than five cases, or to non-unions of other fracture sites. After applying these criteria 9 papers[24,16,25-28,17,29,30] were found eligible for further evaluation (Table 2). The accumulated data were extended also to the studies cited in the retrieved papers.

Simultaneously, according to the guidelines of the existing health economic literature[31-33], we conducted a cost-identification analysis[34] of the treatment of long-bone fracture non-unions in a "best-case scenario".[35,32] Depending on the specific site of the long-bone fracture and the consequent non-union, the overall course of treatment and economic burden varies. For practical reasons we have decided to divide our analysis into humeral non-unions (HN), femoral non-unions (FN) and tibial non-unions (TN). The costs of treatment were calculated using the estimate for the year 2006-2007 provided by the Finance Department of our hospital. As a "best-case scenario" we have defined the case of an established non-union, which 6 months post injury shows no signs of clinical or radiological healing, and after one additional operative or non-operative intervention progresses to fracture healing with no further interventions or complications.[1]

The time till bone healing and return to a pre-injury level of activities or close to it, the occurrence of any new local or systemic complications, and the unique characteristics of each patient, all influence the total socioeconomic burden. Thus a worst-case scenario was not assessed due to the complexity of such an analysis at a theoretical level.[32]

Results

Literature review

The existing literature exploring the economic aspects of long-bone fracture non-unions starts in the mid-1990s. Firstly in 1994, the study of Williams[30] analysed the hospital costs and professional fees (direct medical costs) of treating tibial non-unions, infected or not, resulting after

Table 2
Papers referring to economic costs of non-unions of long-bone fractures

Author(s)	Year	Fracture Site-Type-(Number)	Treatment	Currency	Costs	
					Type	Amount
Williams[30]	1994	Complicated tibial diaphyseal # - Open grade III (10)	Ilizarov vs. amputation	US$	DMC-(HC)	59,213.71 vs. 30,148.02 (403,199.18[a])
Heckman et al.[27]	1997	Tibial diaphyseal # (1000)	Low intensity U/S and Conservative or Operative	US$	DMC, INDC	23,246-58,525
Beaver et al.[24]	1997	Tibial diaphyseal # non-unions (9/11)	Operative	US$	DMC	11,333
Downing et al.[26]	1997	Tibial diaphyseal # (39)	Conservative vs. IMN	£	DC, INDC	(6,700)
Sprague and Bhandari[17]	2002	Tibial diaphyseal closed # (35)	Early[b] vs. Late plate fixation	CAN$	DC	530.56-2,885.28
Vinken et al.[29]	2003	Tibial diaphyseal # non-unions (n/a)	BMP-7 vs. Ilizarov vs. Autograft	€	DMC	13,899[c] (15,156[d]) vs. 15,361[c] (n/a) vs. 14,353[c] (14,348[d])
Busse et al.[16]	2005	Tibial diaphyseal closed/open IA # (n/a)	Casting vs. Casting & U/S vs. IMN (±reaming)	CAN$	DC, INDC	11,749 vs. 11,801 vs. 11,778
Patil and Montgomery[28]	2006	Complicated Tibial and Femoral diaphyseal # non-unions (41)	Ilizarov frame	£	DMC	29,204
Dahabreh et al.[25]	2006	Persistent Tibial-Humeral-Femoral diaphyseal # non-unions (25)	BMP-7 ± autografts	£	DMC	7,338.50

£, British pound; CAN$, Canadian dollar; DC, Direct costs (medical and non-medical); DMC, direct medical costs; HC, hospitalisation costs; INDC, indirect costs; IMN, intramedullary nailing; n/a, not available; U/S, therapeutic low intensity pulsed ultrasound; US$, United States dollar.
[a] Direct Medical Costs if also the expenses for lifetime prosthetic limp are included.
[b] Early fixation ⩽12 hours.
[c] United Kingdom's costs; [d] Germany's costs.

severe trauma (open fractures grade III[36]). The direct aim of that study was to provide arguments in favour of the treatment of these extreme cases with an Ilizarov frame, instead of the alternative of an acute amputation. The direct medical costs of the final treatment were estimated to the level of US$59,213.71 for the Ilizarov group, and US$30,148.02 for the amputations. The latter group's expenses however were raised to US$403,199.18 if lifetime prosthetic costs were included.

Heckman et al.[27] in 1997 utilised three different economic models of the overall direct and indirect costs from a pool of 1,000 tibial diaphyseal fractures. Their aim was to quantify the cost of treating fractures that become delayed unions. They analysed separately those treated with low-intensity pulsed ultrasound as a supplementary measure of operative or conservative treatment schemes. In both treatment schemes the use of the ultrasound device offered savings of US$13,259-15,219 per case due to a statistically significant reduction of delayed- and non-unions rates (from 36% to 6%). In all the different scenarios of successful treatment the overall (Surgery, Recovery, Outpatient, Worker's Compensation, and Disability) costs ranged from US$23,246 to US$58,525.

In the same year two more studies of tibial shaft non-unions, originating from the USA, denoted the rapidly growing scientific interest. Beaver et al.[24] analysed the records of 11 patients with tibial non-unions in order to provide some evidence of the burden these complications represent. On average, the total inpatient and outpatient charges per week were US$694 (range 253-1467) and US$21 (range 11–43), respectively. At their institution the direct medical costs reached the sum of US$11,333 (range 2,165–23,279). These authors also managed to describe the differences in expenses between infected and aseptic non-unions. Infected tibial non-unions averaged 8.8 operations till healing vs. 5 for the aseptic, and their average cost was US$13,739 vs. US$9,407 respectively.

In the study of Downing et al.[26] the economic aspects of conservative or operative treatment with intramedullary nailing was compared. The authors evaluated the actual direct costs of each treatment till union, including an assessment of the actual cost of days off work per patient. With all these economic parameters taken into account both treatment options had a cost of £6,700 (prices of 1993). The fact that non-unions only occurred in patients treated conservatively kept the authors from drawing a clear estimation of the actual cost of this complication.

Additional indirect data of the cost of tibial non-unions have been reported by Sprague and Bhandari in 2002.[17] In their thorough analysis of the effect on health economics of delayed vs. early fixation of tibial shaft fractures, they assessed the costs of each treatment complication. Non-union was observed only in the delayed IMN group (42.1%). Its direct medical/non-medical and indirect costs were calculated to be CAN$33.16-180.33 per week till final bone union. Taking into consideration that on average a 16-week delay of union was recorded, one can assume that the economic burden of the tibial shaft non-unions ranged between CAN$530.56 and 2,885.28 (prices of 2000–1).

Vinken et al.[29] the next year reported significant evidence concerning the actual cost of the treatment of tibial non-unions in two different European countries. Tibial shaft non-unions treated with bone morphogenic proteins (BMP-7-Osigraft) had a cost per UK patient of €13,899. If treated with Autograft the costs were €14,353, and €15,361 for the Ilizarov frame group. In Germany the same treatment options had a cost of €15,156 per patient treated with BMP-7 and of €14,348 for those treated with Autograft. The cost-effectiveness ratio was comparable between the different treatment options.

The management strategies of tibial shaft fractures have been again used as an example for economic analysis in 2005 by Busse et al.[16] They made a thorough accretion of data concerning direct healthcare costs, out-of-pocket direct non-medical expenses, and also productivity losses based on time to fracture healing. They focused on four different treatment strategies of closed or grade IA tibial diaphyseal fractures (casting, casting & therapeutic ultrasound, unreamed IMN, and reamed IMN). Uncomplicated fractures had treatment and productivity costs of CAN$14,361, 12,006, 13,832 and 11,815 respectively for each treatment strategy. As expected the incidence of the complication of a delayed or a non-union were significantly different between the different treatment modalities (20%, 6.4%, 12.8%, and 3.7% respectively). The additional expenses of the non-unions were found per case to be CAN$11,749, 11,801, 11,778 and 11,778 for the 4 different groups.

In 2006 Patil and Montgomery[28] published their significant work focused on tibial and femoral septic and aseptic non-unions treated with an Ilizarov frame. The mean number of operations undergone prior to the surgical intervention of the authors was 3 (range 1-10), and the mean time of referral was 15.9 and 25.6 months post-injury depending on the presence of a local infection. The estimated costs were derived from the 2004-2005 assessment of the Finance Department of their hospital, and were limited to the final phase of treating these 41 complicated cases with an Ilizarov frame. The average expenses reached the sum of £29,204 and represented the direct medical costs of this treatment option.

Dahabreh et al.[25], in their recent cost analysis of persistent tibial non-unions, assessed the economic basis of the use of BMP-7. They analysed 25 fractures with at least 2 previous operations that had failed to lead to bony union at the fracture site. Their economic analysis reflected the direct medical costs of all the in-hospital and outpatient treatments from the initial injury event. As a final phase of their treatment the patients were grafted with BMP-7 in all cases, and additional autograft was used in 64%. A total of 127 hospital admissions, a mean hospital stay of 34.08 days (range 5-154) and a mean of 5.36 operations per fracture (range 1-23) were recorded. The average total cost of treatment per fracture that develops a non-union was found to be £21,183.05 (range 6,702.2-79,915.2). The same calculation of the costs for the same fractures, if they have followed an uncomplicated clinical course, produced an estimate of £3,003.5, £3,119 and £3.111 till clinical and radiological union of a humeral, femoral, or tibial shaft fracture, respectively. The net costs of treating a non-union succesfully with BMP-7 had an average of £7,338.37 which was on average 47% less than the costs of all the previous unsuccessful interventions.

"Best-Case Scenario" cost identification

The direct medical and non-medical costs per case of non-unions treatment are listed in Table 3 separately for each long bone. As a "best-case scenario" for each of the different fracture sites - HN, FN, TN - we consider the aseptic case where by utilising the gold standard method of treatment, according to the literature, the minimal antibiotic prophylaxis of 3 doses, a standard period of thromboprophylaxis, a standard number (5) of outpatient visits and investigations, a minimum number of physiotherapy sessions (10), clinical, radiological healing and return to work occurs at an average time of 6 months post non-union operative intervention. No additional complications or interventions are included, and the functional outcome is assumed to be optimal.

According to the 2006 annual report of National Statistics the median weekly pay for full-time employees in the UK was £447 (top 10% >£ 886; bottom 10% <£244). The indirect costs (lost wages of patients and relatives, impairments and household help) were all calculated in prices of the financial year 2006.[18] The National Statistics Office also provides estimates for the expenditures on Adult Social Care (ASC) services, and on Personal Social Services (PSS). For the years 2003-2004 the average of Residential and Nursing care for adults with physical disabilities (permanent or temporary) was £574 per person per week. For the same period of time the average direct payments for the same group of patients was £210.[19]

For a humeral fracture non-union, treated with compression plate fixation and grafting (gold standard)[40,41], with a length of in-hospital stay of 4 days, 4 outpatient clinic visits and when the union is achieved at the mean reported time of 4 months[40,41], the best-case scenario cost is approximately £15,566. In a best-case scenario of femoral or tibial fracture non-union with exchange nailing the cost is estimated at £17,200 and £16,330 respectively.[42-44] These expenses are mostly consistent with the acquired data from the existing literature review.

Discussion

Medical spending on injuries in 1987 was 64.7 billion US dollars and in 2000 accounted for 10.3% of total medical expenditures and reached the level of US$117.2 billion.[45,46] In the USA long-bone fractures account for about 10% of all non-fatal injuries[46], and according to the National Medical Expenditure Survey are the number 1 category of injuries as a far as inpatient expenditures.[45] A large part of this huge sum of monetary expenses has to be attributed to their complications, and thus to non-unions.[47,48]

Our literature review exposes just the tip of the problem, as the inconsistency of the methodology between the different studies limits the strength of these evidences. The vast majority of the published orthopaedic economic evaluations have been cost-identification or cost-minimization analyses.[31]

In this series of papers the comparison of different non-union treatment strategies on an economic basis has been utilised in order to provide arguments in favour or against them. The Ilizarov ring fixator system[28,30], the use of BMP-7[25,29] and the application of therapeutic ultrasound[16,27] have been the most popular subjects of investigation. One could argue that

Table 3
Estimates of current economic costs of treatment of long-bone fracture non-unions per patient on a best-case scenario[a]

Item	Expenditures		
	Humeral non-unions	Femoral non-unions	Tibial non-unions
Direct costs			
(I) Medical			
Hospitalisation (per day)			
Ward stay	200	200	200
HDU stay	900	900	900
ICU stay	2,000	2,000	2,000
Operating Theatre Sessions, × No. of operations	800	800	800
Anesthesiology session	350	350	350
Implants[37] - ORIF-plating	1,003.5	1,254	1,254
Implants[37] - Exchange Nailing	1,480	1,598	1,723
Implants[37] - Ilizarov frame	2,520	2,520	2,520
Removal of Ilizarov	1,024.2	1,024.2	1024.2
Iliac crest Autograph harvesting	573	573	573
BMP-7 per vial[38]	3,002.2	3,002.2	3,002.2
Supplementary treatments			
EXOGEN - Bone Healing System[39]	765	765	765
Orthopaedic supplies (crutches, plaster, casts)	30[b]	90[b]	90[b]
Drugs - Medications administered, × No. of doses/units[39]			
Vancomycin per 1 g inj iv	4.65	4.65	4.65
Cefuroxime per 750 mg inj iv	0.94	0.94	0.94
Pain killers - co-codamol per tabl 500mg	0.23	0.23	0.23
LMWH prophylaxis - enoxaparin 40 mg inj sc	n/a	12.34	12.34
Blood transfusion per unit	132	132	132
Investigations			
Haematology, × No. of samples	4	4	4
Microbiology, × No. of samples	15[b]	15[b]	15[b]
Radiology , × No. of X-rays	61.5[b]	61.5[b]	61.5[b]
× No. of CT	450	450	450
× No. of MRI	550	550	550
Outpatient Clinics, × No of appointments	71	71	71
Physiotherapy & Rehabilitation, × No. of appointments	28	28	28
(II) Non-medical			
Transportation, × No. of visits	107[b]	107[b]	107[b]
Lodging of relatives, × No. of days	n/a	n/a	n/a
Indirect costs[18, 19]			
Lost wages, per person per week off work	447[b]	447[b]	447[b]
Impairments -social benefits and compensation, per person per week	210[b]	210[b]	210[b]

CT, computed tomography; d, days; HDU, high dependency unit; ICU, intensive care unit; inj, injection; iv, intravenous; LMWH, low molecular weight heparins; MRI, magnetic resonance imaging; N, number; n/a, not applicable or available; ORIF, open reduction internal fixation; sc, subcutaneous injection; tabl, tablets.
[a] Estimates are presented in British pounds £ financial year 2006-2007; VAT 17%.
[b] Median values

the stimulus for these analyses could be the high flat cost, and also the novelty of these treatment options in comparison with more traditional and cheap options. However, with their results the authors have confirmed the fact that the actual economic burden of a treatment method is a complex entity and should not be judged from implant costs alone.[49,21,20] Full economic evaluation of a treatment method or of a sickness requires an analysis of direct, indirect and also of the monetised quality of life aspects.[31,49,14] Half of those which are referring to long-bone fracture non-unions are restricted to the direct medical costs.[24,25,28-30] The other 5 studies[16,26,27,17] have taken into account both direct and indirect costs of their cases. The inpatient costs represent 87–94% of the direct medical costs.[24] Moreover, it is estimated that the indirect costs for musculoskeletal conditions represent about 80% of the total costs of these conditions, with 20% as direct costs.[31]

As a model for an economic analysis the vast majority of the authors have used the tibial diaphyseal non-unions.[24,16,25-28,17,29,30] This can be attributed to the fact that the tibia is the most commonly fractured long bone and has a non-union incidence of 4.4%.[42,43] Non-unions complicate femoral and humeral shaft fractures at rates close to 6% and 10–15%, respectively.[1,40,3,41] The lack of existing evidence on humeral non-unions and the overall scarcity of long-bone fracture non-union data dictate some of the priorities of any future health economic research.

Our cost-identification inquiry identified the current separate prices and expenses of most of the different modes of treatment of long-bone fracture non-unions. If an uncomplicated course occurs, for a standard type of patient, with no special level of activities and demands, then this is a "best-case scenario" and is only relevant to the treatment strategy that has been followed. For a HN the cost is estimated around the sum of £15,566, for FN around £17,200 and for TN around £16,330. Any existing discrepancies with the described expenses of the different studies can be attributed to differences in currency, to the annual inflation, the variety of countries and health systems, and of course to the different treatment strategies.

Conclusions

Clinicians need to consider both clinical outcomes and economic factors when evaluating treatment options, or even when making clinical decisions. Patients treated for a long-bone fracture non-union are submitted to frequent hospital admissions and a number of interventions. The lengthier the treatment of a non-union, the higher is also the risk of developing additional complications, and of course the greater the financial burden to the healthcare system.

The existing scientific evidence can only imply the extent of the problem. Further systematic studies are needed assessing the direct medical, direct non-medical, indirect and monetised quality of life and psychosocial costs of non-unions.

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