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Osteopathic care for low back pain and neck pain: a cost-utility analysis

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Highlights

- Health economic evaluation studies of osteopathic care for low back pain and/or neck pain are scarce. Information from such studies is however valuable providing information that can aid policy makers in their decision making process

- The findings of the current study suggested that osteopathy, compared to usual care, was found to be a dominant strategy (i.e. having a higher effect at lower costs) for low back pain and a cost-effective strategy for neck pain

- Further research applying a societal perspective and also taking into account the long-term consequences of osteopathic care for low back pain and neck pain is required

Abstract

Objectives The aim was to examine the health and economic consequences of osteopathic care for low back pain and neck pain in addition to usual care compared to usual care alone.

Design A decision tree model considering a one-year time horizon was applied. The analysis occurred from a health insurance perspective only considering direct medical costs. The health effects were expressed as quality-adjusted life years (QALYs).

Main outcomes

The main outcome was the incremental cost-effectiveness ratio (ICER). The uncertainty around key input parameters was addressed applying one-way and probabilistic sensitivity analyses (5,000 simulations).

Results For low back pain, osteopathy resulted in cost savings (€385.1 vs €501.8/patient) at improved QALYs (0.666 vs. 0.614) compared to usual care. For neck pain, osteopathy resulted in additional costs (€577.3 vs. €521.0) and improved QALYs (0.639 vs. 0.609) resulting in an ICER of €1,870/QALY. The one-way sensitivity analysis identified the hospitalization cost (back) and osteopathy cost (neck) as major cost drivers. The probabilistic sensitivity analysis resulted in an average net saving of €163 (95%CI -€260, -€49.1) and a QALY gain of 0.06 (95%CI -0.06, 0.17) for low back pain and an average additional cost of €55.1 (95%CI €20.9, €129) and improved QALY gain of 0.03 (95%CI -0.06, 0.12) for neck pain.

Conclusions Osteopathy was found to be a 'dominant' (low back pain) and cost-effective strategy (neck pain) compared to usual care. Further health economic evaluation studies considering a broader range of cost items and longer time horizon are required.

INTRODUCTION

Low back pain (LBP) and neck pain are common conditions with prevalence ranging from 15% to 45% for LBP (1) and from 30% to 50% for neck pain (2). These spinal complaints represent a major medical, social and economic burden including healthcare utilization, absence from work, impact on activities and impaired quality of life (3-5). Osteopathy as a form of manual medicine is a common treatment option and, worldwide , its use has increased in the past decades (6, 7). Osteopathy can be defined as a primary contact and patient-centred healthcare discipline, that emphasizes the interrelationship of structure and function of the body, facilitates the body's innate ability to heal itself, and supports a whole-person approach to all aspects of health and healthy development, principally by the practice of manual treatment (8). International differences in osteopathic healthcare regulation influence its scope of practice (6), which may explain some of the differences between US and, European and Australasian osteopathic healthcare provision. Although, osteopathic training in Belgium is very heterogeneous, as seems to be the case for most European countries (9), 85% of the osteopaths already has an academic degree in physiotherapy prior to their part-time 4 to 6 year osteopathic training (6).

Belgian osteopaths are most frequently consulted by patients with spinal complaints, which is in accordance with studies in Spain, UK and Australia (10-13). The prevalence of osteopathic healthcare in Belgium has been reported at 6% of the general population (14) and the total number of osteopathic consultations per year has been estimated at 2.5 million (12, 15). Because osteopathic care is not included in “mandatory health insurance” in Belgium, its reimbursement is organized through additional private health insurance. This makes the patients of osteopathic practices in Belgium predominantly private fee-paying.

The findings of previous literature reviews suggested clinically relevant impact on pain and functional status of osteopathic care for LBP (16-18) and neck pain (19). The reviews however concluded that further research with larger sample sizes, robust comparison groups and assessing the long-term effects of osteopathic care for LBP and neck pain is required. In the review by Licciardone et al. (18), it was also concluded that research evaluating the cost-effectiveness of osteopathic care as complementary treatment for LBP and neck pain is needed. Indeed, solely evidence on the effectiveness of osteopathic care for these indications is insufficient for policy making. The growing number of health economic evaluation studies (20) reflects the increasing interest in economic information for new or alternative treatment strategies together with clinical efficacy (21). This is largely caused by increasing budget constraints and rising demands for evidence-based healthcare spending (22). Governments are facing the problem how to set priorities in the allocation of healthcare resources to treatment strategies. Such knowledge can be obtained by health economic evaluation studies of treatments providing better insights how to spend the available resources in the most efficient way. With the current study, a health economic evaluation study for the Belgian situation was conducted assessing the value for money of osteopathic care in addition to usual care compared to usual care alone for LBP and neck pain.

METHODS

Decision model

Decision-analytic modelling is considered as a convenient tool for health economic evaluations of new or alternative strategies compared with standard ones (23). In the current study, a decision tree model was used. The model predicts health outcomes – expressed as quality-adjusted life years (QALYs) – and costs over a one-year time horizon. This time period was divided in an intervention period of three months and a nine-months follow-up period. The choice for a three-months intervention period was based on previous studies showing that osteopathic care for spinal complaints was usually limited to a maximum of three months (24-29). QALYs were calculated by multiplying the utility level for a given condition (a health-related quality of life weight ranging from zero to one) with the time period an individual lived with the particular condition. A utility of one is equal to perfect health, while zero stands for death. The study was conducted from a health insurance perspective taking into account the direct costs associated with LBP and neck pain treatment. The ratio of the incremental costs to the incremental health effects is called the incremental cost-effectiveness ratio (ICER) calculated as $Cost_{intervention} – Cost_{control} / Effect_{intervention} – Effect_{control}$ (22).

A similar model for the two indications (LBP and neck pain) was developed (Figure 1). In the decision tree model, two strategies were compared including (1) care administered by an osteopathic practitioner above usual care and (2) usual care alone. Usual care included a general practitioner (GP) consult, pain medication, physiotherapy and/or rehabilitation, medical imaging, and hospitalization. A first distinction in the model was based on whether or not the patient experienced clinically meaningful pain improvements (i.e. the response rate). This was defined as a mean improvement in pain score on the Visual Analogue Scale (VAS) or the Numerical Rating Scale (NRS) of ≥2 points (30, 31). In all branches of the model, an initial assessment by a GP was assumed. In case of a clinically meaningful pain improvement, it was assumed that, during the nine-month follow-up period, the patient remained on medication, however at a lower dose than those without significant pain reduction without any other care required. In case of no pain improvement, further treatment including only medication, medication together with ambulatory care (physiotherapy and/or rehabilitation), or medication together with hospitalization was assumed.

<insert Figure 1>

Data sources

Clinical data

Information about the response rate of osteopathic care vs. usual care was derived from previous research. For the base case analysis, studies had to meet the following criteria to serve as input: (1) a randomized controlled trial (RCT) design, (2) a European study, (3) impact on pain assessed by the VAS or NRS, (4) an intervention duration of maximum three months, and (5) reporting mean [95%CI] change in pain. For LBP, five studies were found to be eligible (25, 32-35), while for neck pain information on response rate was derived from two studies (28, 36). In none of these studies, the proportion of patients experiencing clinically meaningful pain improvements was reported. So, for each study, we estimated the response rate using the mean±SD [95% confidence intervals] (Table 1). Subsequently, a weighted average response rate was calculated based on the response rate/study and the number of participants in each study (Table 1). For LBP, an average response rate of 88.3% in the intervention group and 23.1% in the control group was estimated. For neck pain, these figures were 55.3% and 22.6% in the intervention group and control group, respectively.

Table 1 Input data for the estimation of the response rates osteopathic care vs. usual care in LBP and neck pain

study	number of participants		mean [95%CI] pain improvement		estimated response rate	
	intervention	control	intervention	control	intervention	control
low back pain						
Heinze (32)	30	30	4.3 [3.5,5.1]	1.8 [1.0,2.6]	0.85	0.46
Peters (33)	30	27	4.4 [3.5,5.2]	-0.3[-1.0,0.4]	0.84	0.11
Belz (25)	27	27	4.2 [3.4,5.0]	0.4 [-0.1,0.9]	0.85	0.09
Schwerla (35)	40	40	5.3 [4.8,5.9]	0.5 [0.2,0.9]	0.97	0.11
Recknagel (34)	20	19	4.8 [3.6,6.8]	2.0 [-2.7,6.6]	0.78	0.50
Cruser (37)[£]	30	30	3.3[*]	1.8[*]	0.77[‡]	0.43[‡]
Licciardone (38)[£]	19	15	2.0 [0.9,3.1]	0.3 [-0.7,1.4]	0.50	0.20
Licciardone (39)[£]	230	225	1.8 [0,3.1]	0.9 [-3.0,2.5]	0.63	0.46
Licciardone (40)[£]	175	170	2.0 [0.2,3.6]	0.3 [-0.5,2.5]	0.50	0.47

neck pain						
Schwerla (28)	21	16	2.5 [1.4,3.5]	0.7 [-0.1,1.6]	0.58	0.24
Engemann (36)	15	15	2.1 [0.6,3.6]	-0.3[-1.8,1.2]	0.52	0.21
McReynolds (41) £	29	29	2.8 [2.1,3.4]	1.7 [1.1,2.3]	0.68	0.43

CI, confidence interval
‡ response rate reported in the study
* no 95% CI reported
£ additional studies included in the scenario analysis (together with the European studies)

Resource use and cost data

The resource use and corresponding cost components included consultation, ambulatory care, medication, medical imaging, and hospitalization (Table 2). The cost of a consultation with an osteopath was obtained from a survey on the practice characteristics of osteopaths in Belgium (15), while those for a GP and medical specialist consultation were derived from the National Institute for Health and Disability Insurance (NIHDI) nomenclature database (42). Five osteopathic care consultations were considered (25) and one GP and medical specialist consultation. In case of no clinically meaningful pain improvement, an additional GP contact was assumed. Information about ambulatory care and medication use were obtained from a study on resource use and associated costs for patients suffering from LBP in Belgium (43). Medication use was limited to prescribed and reimbursed drugs (non-steroidal and anti-inflammatory drugs and narcotic analgesics). In the 'clinical improvement' arm of the model, the medication costs were halved based on the assumption that these patients would need less medication. The proportion of patients receiving ambulatory medical imaging and the proportion being hospitalized were obtained from the study by Nielens et al. (43). The costs for medical imaging and hospitalization were obtained from publicly available data (42, 44). For neck pain, no information on resource use for medication use, ambulatory care, medical imaging, and hospitalization was available. So, for these input parameters, the values used for LBP were used. Medication costs, ambulatory care costs, and hospitalization costs were actualized to account for the year 2015 euros. No discounting of costs was applied since the time horizon was limited to one year (22).

Table 2 Resource use, unit costs (€) and costs used in the decision tree model LBP and neck pain

resource	number/proportion		unit cost (€)	costs in the model				source
	pain improvement	no pain improvement		pain improvement		no pain improvement		
				0-3 months	4-12 months	0-3 months	4-12 months	
consultations								
osteopath	5	5	50.0	250		250		(15)
GP	1	2	20.9	20.9		41.8		(42)
medical specialist	/	1	41.1			41.1		(42)
medication	0.5	1	68.0	10.4	31.3	20.8	62.5	(43)
ambulatory care								
physiotherapy	/	45.6%	289			32.9		(43)
rehabilitation	/	27.3%	303			20.7		(43)
physio + rehab	/	27.1%	592			40.1		(43)
physiotherapy 4-12m	/	35.7%	289				98.9	(43)
hospitalization	/		5,605			5,605		(44)
medical imaging	/							
x-ray lumbar spine		18.0%	40.2			7.3		(42, 43)
x-ray cervical spine		18.0%	45.2			8.2		(42, 43)
CT		13.0%	131			17.0		(42, 43)
NMR		5.4%	118			6.4		(42, 43)

CT, computed tomography; GP, general practitioner; NMR, nuclear magnetic resonance

Health-related quality of life

Utilities were derived from published literature (Table 3). For LBP, they were obtained from the cost-effectiveness analysis of the 'UK back pain exercise and manipulation (UK BEAM)' study (45). In that study, utilities were reported making no difference between responders and non-responders. So, to reflect a higher health-related quality of life for patients experiencing clinically meaningful improvements, we calculated an adjusted utility for responders taking into account the calculated average response rate of 88.7%. For neck pain, the utilities were derived from a study of predicting utility scores from the neck disability and NRS (46). QALYs were not discounted since the time horizon of the model was limited to one year (22).

Table 3 Utilities used in the decision tree model for low back pain and neck pain

input parameter	low back pain	neck pain	source
pain improvement	0.676	0.680	(45, 46)
no pain improvement			
medication	0.595	0.630	(45, 46)
ambulatory care	0.595	0.560	(45, 46)
hospitalization	0.595	0.490	(45, 46)

Sensitivity and scenario analyses

Health economic evaluation studies are frequently characterized by some degree of uncertainty or methodological considerations (22). One-way sensitivity and probabilistic sensitivity analyses were conducted to handle this uncertainty. One-way sensitivity analysis made it possible to evaluate the effect of key input parameters (resource use and cost parameters) on the outcome by varying them separately. A uniform 50% to 150% uncertainty was applied. A probabilistic sensitivity analysis, based on 5,000 simulations, was performed to assess the uncertainty for key input parameters by varying them concurrently. Cost data were assumed to follow a gamma distribution, and utilities and response rates a beta distribution (22). In addition, a scenario analysis was performed also taking into account studies from other countries than European ones. For LBP, this resulted in four additional studies (37-40) that met the above mentioned inclusion criteria and were included into the scenario analysis. For neck pain, one extra study was included (41). An overview of these studies can be found in table 1. So, for LBP, the weighted average response rates were based on eight studies and for neck pain on three studies.

RESULTS

Base case analysis

For LBP, osteopathic care was found to be a cost saving strategy/patient compared to usual care (osteopathy: €385.1 vs. usual care: €501.8; difference: €116.7) at improved QALYs (osteopathy: 0.666 vs. usual care: 0.614; difference: 0.052). For neck pain, osteopathic care resulted in additional costs/patient compared to usual care (osteopathy: €577.3 vs. usual care: €521.0; difference: €56.3), however at improved QALYs (osteopathy: 0.639 vs. usual care: 0.609; difference: 0.030) resulting in an ICER of €1,870/QALY.

Sensitivity analyses

The findings from the one-way sensitivity analyses are shown using Tornado diagrams (Figure 2a and b). For both LBP and neck pain, the major cost drivers were the cost of an osteopathic consultation, the hospitalization cost, and the probability of hospitalization. Varying the other input parameters had only minor influence on the outcomes.

<insert Figure 2a&b>

The findings of the probabilistic sensitivity analysis showed that, for LBP, osteopathic care resulted in an average net saving of €163/patient (95% CI -€260, -€49.1) and an average QALY gain of 0.06 (95%

CI -0.06, 0.17) compared to usual care. For neck pain, osteopathic care resulted in an additional average cost of €55.1 (95% CI €20.9, €129), yet at an average QALY gain of 0.03 (95% CI -0.06, 0.12). The findings of the 5,000 simulations are shown in cost-effectiveness planes (Figure 3a and b) to a great extent confirming the results from the base case analysis.

<insert Figure 3a&b>

Scenario analysis

The results from the scenario analysis also considering the findings from studies from other countries than European ones suggested that, for both LBP and neck pain, osteopathic care resulted in additional costs/patient compared to usual care (*LBP*: osteopathy: €509.9 vs. usual care: €386.5; difference: €123.4; *neck pain*: osteopathy: €537.5 vs. usual care: €451.1; difference: €86.4), yet at improved QALYs (LBP: osteopathy: 0.648 vs. usual care: 0.630; difference: 0.018; *neck pain*: osteopathy: 0.644 vs. usual care: 0.617; difference: 0.026). This results in an ICER of €5,039/QALY and €6,878/QALY for LBP and neck pain, respectively.

DISCUSSION

The results of health economic evaluation studies are often expressed in the form of an ICER representing the difference in costs divided by the difference in effects of two or more treatment strategies (22). For neck pain, an ICER of €1,870/QALY was observed. Yet, an ICER as such does not allow to draw conclusions whether or not a treatment strategy can be considered as cost-effective. It requires a comparison with a reference value above which the strategy would not be considered cost-effective. The average gross domestic product per capita could serve as such a reference value representing a value of about €35,000 for Belgium (47). So, for neck pain, the osteopathic treatment strategy is below the threshold and can thus be considered to be cost-effective compared to usual care. For LBP, osteopathy was found to be a cost saving strategy at improved health (expressed in QALYs) compared to usual care. In health economic terms, such a result is called 'dominant' since osteopathy was found to have a higher effect at lower costs compared to usual care (22).

Health economic evaluation studies of osteopathic care for LBP or neck pain are scarce. Two such previous full economic evaluation studies were identified (45, 48). Williams et al. (48) conducted a cost-utility analysis of osteopathic care for subacute neck, upper or LBP in addition to GP treatment compared to GP treatment alone. At six months, a non-significant mean difference in total healthcare costs (intervention vs. control, £328 vs. £307) was observed. A mean difference of 0.056 QALYs in favour of osteopathic care was identified (0.722 vs. 0.665). This resulted in an ICER of

£3,560/QALY. Assuming a £30,000 cost-effectiveness threshold in the UK, the osteopathic care intervention could be considered a cost-effective strategy. In our study, similar QALY differences between osteopathic care and usual care were observed for LBP (0.057) and lower for neck pain (0.030) compared to the findings form the study by Williams et al. (48). Comparing the results across studies is yet difficult due to methodological differences such as study populations, time horizon, utility data sources. In another cost-effectiveness study in the UK, manipulation together with exercise was found to be a cost-effective strategy compared to 'best care' for back pain (ICER: £3,800/QALY (45). Both previous health economic evaluation studies were conducted alongside a RCT, thus using input data from the clinical trial. For our study, no information from an accompanying trial was available. So, inputs were derived from previous studies and from publicly available data sources. As a consequence, uncertainty related to the values included in the decision tree model could be assumed. On the other hand, the inputs related to the response rate of osteopathic care vs. usual care for LBP and neck pain were obtained from RCTs. Such trials are the gold standard in editing clinical trials whereby individuals are randomized to either intervention or control groups (49). It is important to present results of cost-effectiveness analyses in a transparent way, while exploring the uncertainty in key parameters and pay attention to validating the model and the model outcomes (50). In the current study, the uncertainty was addressed using one-way sensitivity analyses and probabilistic sensitivity analyses (23). In the one-way sensitivity analysis, a uniform 50% to 150% uncertainty was applied identifying the osteopathic consultation cost, the hospitalization cost, and the probability of hospitalization as the input parameters having most influence on the outcomes. The reason for using a uniform uncertainty level for all input parameters included in the one-way sensitivity analysis was to gain insight in those parameters having most influence on the study outcome and not to assess the implications on the study outcome of uncertainty in the parameters. The full uncertainty around key input parameters was reflected with the probabilistic sensitivity analysis. The results from the probabilistic analysis, based on 5,000 simulations was presented using cost-effectiveness planes (23). For LBP, the majority of the simulations were situated in the 'south east' quadrant reflecting osteopathic care inducing less costs at improved health compared with usual care. For neck pain, the majority of the simulations were located in the 'north east' quadrant reflecting osteopathic care to be more expensive however at improved health compared to usual care. The line in the figure represents a cost-effectiveness threshold of €35,000/QALY and the simulations below can be considered as cost-effective.

A number of limitations need to be addressed. First, the effectiveness of osteopathic care compared to usual care was assessed by applying the outcome 'proportion of patients experiencing clinically meaningful pain improvement'. Unfortunately, this information could not be obtained from a published systematic review or meta-analysis. Consequently, information related to the response rate was obtained from individual randomized controlled studies for which we defined a number of criteria that studies had to meet to be eligible for inclusion into the analysis. This may have caused a selection bias. Prior to the current study, we performed a systematic literature study of the effectiveness of osteopathic care for spinal complaints [manuscript in review with PlosOne]. Nineteen studies were included in the review of which 12 (25, 28, 32-41) met the inclusion criteria to serve as input for the base case analysis and scenario analysis of the health economic evaluation study. The remaining studies were not eligible because of not meeting the inclusion criterion 'impact on pain assessed by the VAS or NRS' (29, 51), 'intervention duration of maximum three months' (52, 53), and 'reporting mean [95%CI] change in pain' (24, 26, 27). Keeping the possible selection bias in mind, following guidelines from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (54), we conducted both sensitivity analyses and a scenario analysis to handle the uncertainty around the input parameter 'response rate'. Second, decision models are to some extent a simplification of the often highly complex processes underlying the possible prognoses and treatments a patient can experience (23). For example, for modelling reasons, we assumed a GP visit in every arm of the decision tree model. Based on expert opinion, it can however be questioned if patients suffering from LBP or neck pain always first consult a GP before seeking alternative care options such as osteopathic healthcare. Third, the utilities were derived from published studies (45, 46) and may be subject to some degree of uncertainty related to the Belgian context. Therefore, the uncertainty around the utility values was included in the probabilistic sensitivity analysis. Fourth, the study was conducted from a health insurance perspective only taking into account the direct medical costs associated with LBP and neck pain. It is yet clear that these conditions are also responsible for considerable indirect costs due to lost productivity (1, 55). Future health economic evaluation studies assessing the value for money of osteopathic care for spinal complaints and/or other conditions should ideally also be performed from a societal perspective considering a broader range of costs such as, besides the direct medical costs, direct non-medical costs (for example transport costs) and indirect costs (for example productivity losses due to work absenteeism). Fifth, a time horizon of one year was applied. However, information on the longer term effects on costs and health outcomes of osteopathic care for spinal complaints may be relevant for policy making.

The findings of a recent systematic review of health economics research of osteopathic manipulative treatment concluded that both quantity and quality of health economic evaluation studies are insufficient to effectively inform policy and practice (20). So, with our study, it was the aim to contribute to filling this gap. Based on the findings of the current study, adding osteopathic care to standard care compared with standard care alone can be considered as a ' dominant' strategy for individuals suffering from LBP and cost-effective for individuals suffering from neck pain in Belgium. The findings must yet be cautiously interpreted due to several limitations. Nevertheless, the results provide yet one piece of information that can aid policy makers in their decision making process related to reimbursement of osteopathic care for spinal complaints. Future health economic evaluation studies of osteopathic care for spinal complaints (and other indications) is yet required and these studies should ideally deal with the limitations addressed in the current study.

Author contributions

NV, JS, and LA contributed to the conception and the design of the study. NV performed the analyses. All authors contributed to the interpretation of the analysis. NV drafted the manuscript, while JS, LA and PvD discussed the results and commented to the manuscript. All authors approved the current version of the manuscript.

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Conflicts of interest PvD is an osteopath. The other authors declare that they have no competing interests.

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Figure 1 Decision tree model low back pain/neck pain

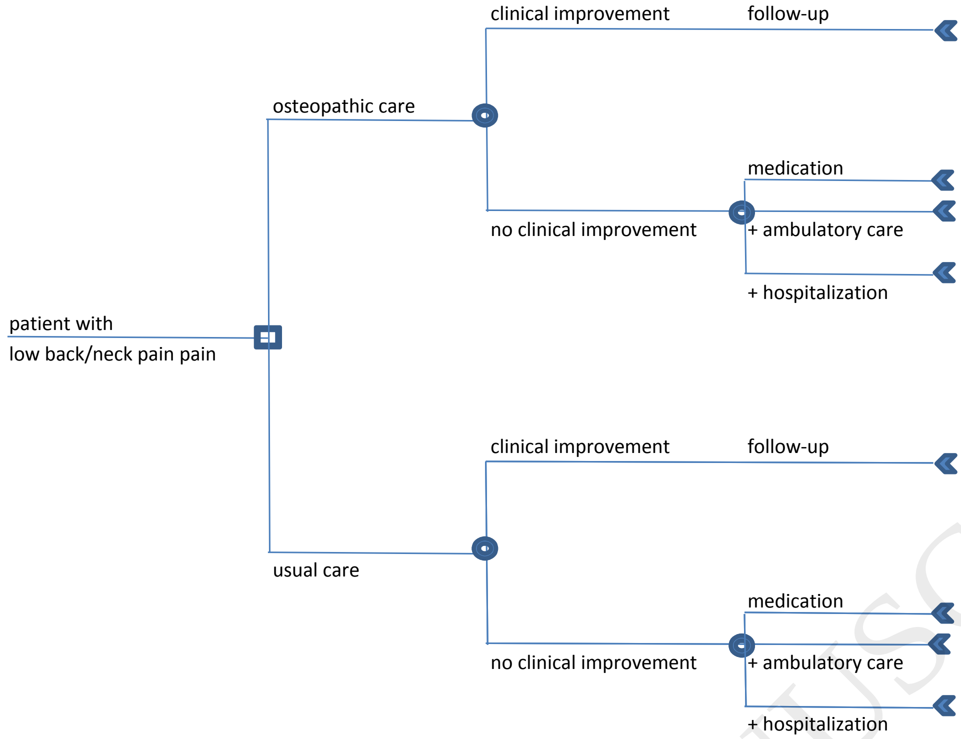

Figure 2a One-way sensitivity analysis: low back pain – effects on ICER

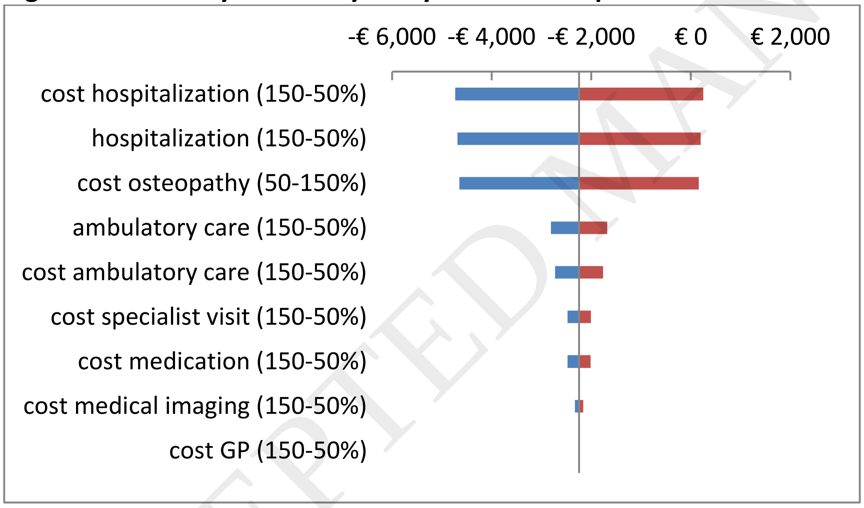

Figure 2b One-way sensitivity analysis: neck pain – effects on ICER

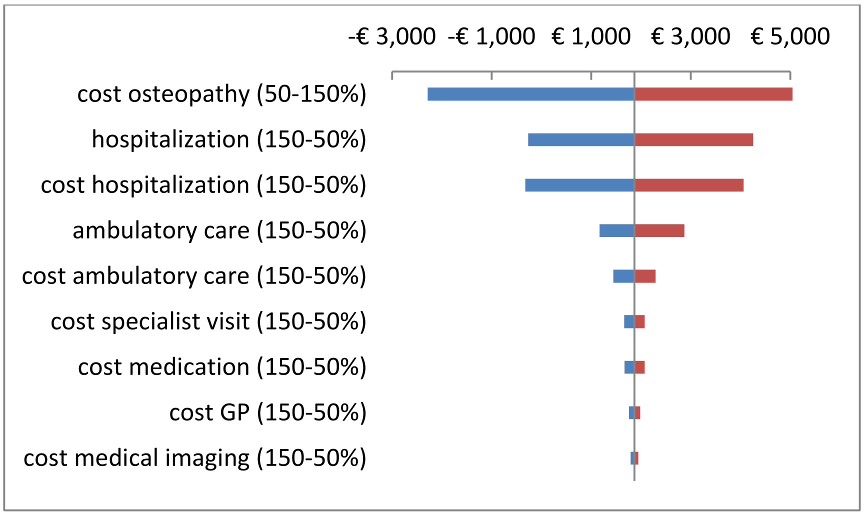

Figure 3a Probabilistic sensitivity analysis: cost-effectiveness plane – low back pain

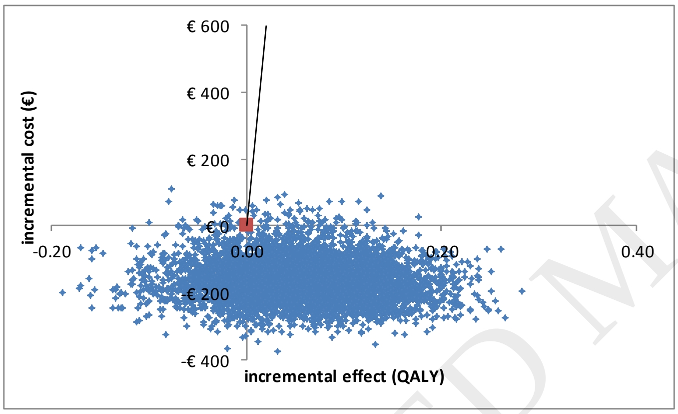

Figure 3b Probabilistic sensitivity analysis: cost-effectiveness plane – neck pain