

Significant Savings with a Stepped Care Model for Treatment of Patients with Intermittent Claudication

H.J.P. Fokkenrood ^{a,g}, M.R.M. Scheltinga ^{b,h}, M.J.W. Koelemay ^c, J.C. Breek ^d, F. Hasaart ^e, A.C. Vahl ^f, J.A.W. Teijink ^{a,g,*}

^a Department of Vascular Surgery, Catharina Hospital, Eindhoven, The Netherlands

^b Department of Vascular Surgery, Maxima Medical Center, Veldhoven, The Netherlands

^c Department of Vascular Surgery, Academic Medical Center, Amsterdam, The Netherlands

^d Department of Vascular Surgery, Martini Hospital, Groningen, The Netherlands

^e Department of Vascular Surgery, CZ, Tilburg, The Netherlands

^f Department of Vascular Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands

^g CAPHRI Research School, Maastricht University, Maastricht, The Netherlands

^h CARIM Research School, Maastricht University, Maastricht, The Netherlands

WHAT THIS PAPER ADDS

The aim of this study was to perform a cost-analysis of a recommended but largely underutilized SET first treatment strategy in intermittent claudication (IC). Until now no study has been performed to investigate the overall economic consequences of a nationwide SET first approach (stepped care). As the study used a large database (3.4 million people), daily practice is reflected well in the results. Implementation of a stepped care treatment for patients with IC may lead to significant savings of healthcare resources. These findings may be generalizable to other European healthcare systems.

Objectives: International guidelines recommend supervised exercise therapy (SET) as primary treatment for intermittent claudication (IC). The aim of this study was to calculate treatment costs in patients with IC and to estimate nationwide annual savings if a stepped care model (SCM, primary SET treatment followed by revascularization in case of SET failure) was followed.

Methods: Invoice data of all patients with IC in 2009 were obtained from a Dutch health insurance company (3.4 million members). Patients were divided into three groups based on initial treatment after diagnosis (t_0). The SET group received SET initiated at any time between 12 months before and up to 3 months after t_0 . The intervention group (INT) underwent endovascular or open revascularization between t_0 and $t_{+3 \text{ months}}$. The third group (REST) received neither SET nor any intervention. All peripheral arterial disease related invoices were recorded during 2 years and average costs per patient were calculated. Savings following use of a SCM were calculated for three scenarios.

Results: Data on 4954 patients were analyzed. Initial treatment was SET ($n = 701$, 14.1%), INT ($n = 1363$, 27.5%), or REST ($n = 2890$, 58.3%). Within 2 years from t_0 , invasive revascularization in the SET group was performed in 45 patients (6.4%). Additional interventions (primary at other location and/or re-interventions) were performed in 480 INT patients (35.2%). Some 431 REST patients received additional SET ($n = 299$, 10.3%) or an intervention ($n = 132$, 4.5%). Mean total IC related costs per patient were €2,191, €9851 and €824 for SET, INT, and REST, respectively. Based on a hypothetical worst, moderate, and best case scenario, some 3.8, 20.6, or 33.0 million euros would have been saved per annum if SCM was implemented in the Dutch healthcare system.

Conclusion: Implementation of a SCM treatment for patients with IC may lead to significant savings of health care resources.

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INTRODUCTION

Recently governments, nongovernmental organizations, and the private sector were called to assess the social and economic consequences of peripheral arterial disease

(PAD) and to explore the best strategies for optimum treatment and prevention of this disease.¹ Although treatment strategies for PAD are well described in international guidelines^{2–4} and advocate a multimodal approach, including medication, lifestyle changes, and symptomatic treatment, mentioning supervised exercise therapy (SET) as the primary treatment option,³ the actual availability of these SET programs worldwide is limited.^{5–9} There is a good availability of SET programs in the Netherlands.¹⁰ However, a proven effective SET program

* Corresponding author. J.A.W. Teijink, Department of Vascular Surgery, Catharina Hospital, P.O. Box 1350, 5602 ZA Eindhoven, The Netherlands.

E-mail address: joep.teijink@cze.nl (J.A.W. Teijink).

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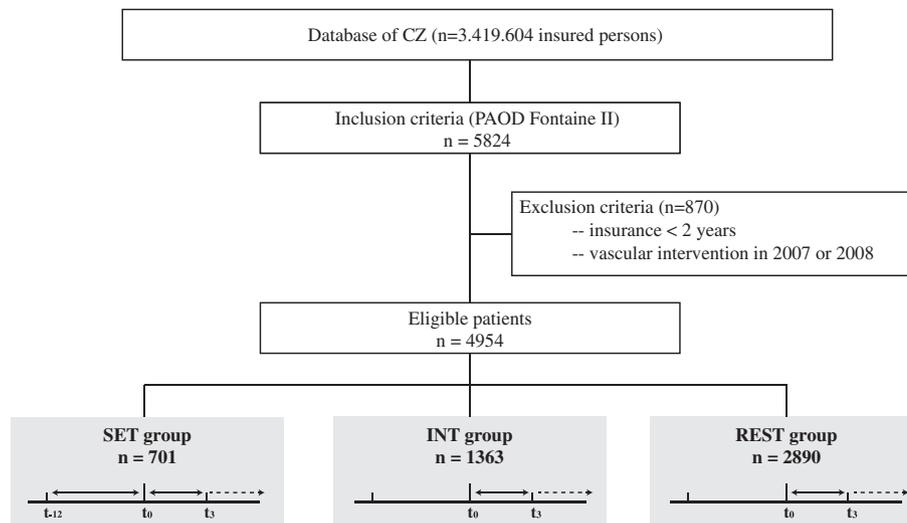


Figure 1. Flow-chart of study population and classification of subgroups. PAOD = peripheral arterial occlusive disease. * straight line: primary treatment; dashed line: secondary treatment.

(performed by physiotherapists trained in improving cardiorespiratory health status as well as lifestyle factors and medication compliance) is in many cases not fully reimbursed.

This reimbursement issue originates from a contradictory policy in the Dutch healthcare system. In the Netherlands, healthcare insurance companies have an obligation to accept everyone for basic healthcare insurance. The Dutch government determines coverage of the standard insurance. In the case of patients suffering from intermittent claudication (IC) the government decided not to cover the first 20 treatment sessions of a SET program, which have to be paid by the patient (either directly or through additional insurance). From the 21st session onwards all additional treatment sessions given in 1 year are covered by the basic healthcare insurance. Medication (prescribed by a physician) and invasive vascular interventions are both included in the standard package and fully reimbursed. As a consequence SET is largely underutilized. Patients may receive proven insufficient and less cost-effective “go home and walk” advice,^{11–14} or a vascular intervention as an alternative first-line treatment strategy,⁵ which contradict contemporary guidelines.

The advocated treatment strategy in the above-mentioned guidelines could be incorporated into a so-called “stepped care” model (SCM).^{5,15,16} This theoretical approach strives to initially refer all IC patients to a SET program and restrict revascularization to those who do not respond to SET. Several cost-effectiveness analyses have been performed supporting such a SET first treatment strategy.^{13,16–20} However, no study has been performed to investigate the overall economic consequences of SCM implementation nationwide. This study is a cost-analysis of SCM implementation in the Dutch healthcare system. Costs of IC treatment were calculated and compared with estimated costs associated with three hypothetical scenarios of nationwide SCM implementation.

METHODS

Inclusion and exclusion

The 2009 database of CZ, a large Dutch healthcare insurance company ($n = 3,419,604$ insured persons, approximately 21% of the Dutch population) was retrospectively analyzed. Insured patients who had received an invoice related to the diagnosis “PAD Fontaine 2” corresponding to IC complaints as diagnosed by a vascular surgeon, were eligible for inclusion. Only patients who had been insured for at least two consecutive years at CZ were eligible, excluding crossover patients from other insurance companies (possibly harboring an unknown 2-year history of PAD). To restrict the study to newly diagnosed IC patients, all patients who underwent vascular interventions in 2007 or 2008 were also excluded (Fig. 1). Data on co-morbidity (diabetes mellitus, COPD, hypercholesterolemia, and heart failure) were collected on the basis of prescribed medication.

Definition of IC subgroups

Patients meeting inclusion criteria were subdivided into three groups based on the primary treatment initiated by

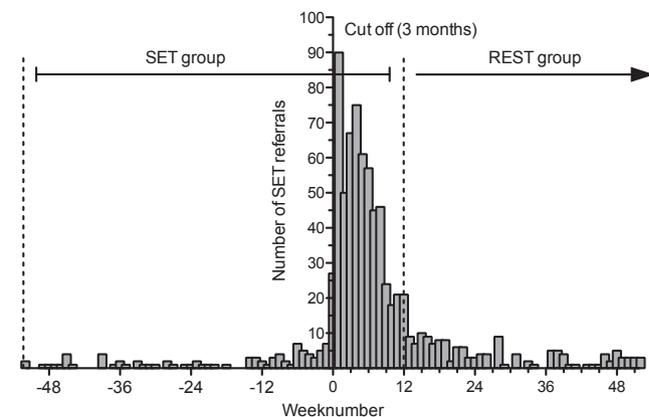


Figure 2. Referral for SET in the SET and REST group 12 months prior and after diagnosis (t_0).

Table 1. Patient characteristics.

	Group			p
	SET	INT	REST	
Number of patients (n - %)	701 (14)	1363 (27)	2890 (58)	
Age (years)	69	65	68	<.001
Gender (% male)	57.3	64.8	58.9	<.001
Diabetes II (%)	6.9	7.0	8.2	=.24
CARA (%)	8.1	10.7	10.1	=.17
Hypercholesterolemia (%)	30.5	29.3	27.4	=.16
Congestive heart failure (%)	9.6	8.7	12.0	<.01

a vascular surgeon within 3 months of diagnosis ($t_0 < t_{3 \text{ months}}$) (Fig. 1).

- SET group: community-based SET started in the period between 12 months prior to diagnosis up to 3 months after the diagnosis of IC by a vascular surgeon (Fig. 2). SET prior to diagnosis was possible in the situation of referral by a patient's general practitioner (GP) who had already initiated SET.
- INT group: Any form of revascularization received within 3 months of diagnosis of IC by a vascular surgeon.
- REST group: Neither SET nor INT group inclusion criteria were met (Fig. 2). It was assumed that these patients received "go home and walk" advice or had no IC at all (this contradictory "no IC in an IC population" phenomenon is explained later).

Secondary treatment was defined as a second intervention (primary at another location and/or re-intervention or SET) performed following primary treatment. This population included patients with failure of primary treatment (re-intervention), treatment of the contralateral leg, or treatment delay (treatment $> t_{3 \text{ months}}$). Differentiation between these groups was not possible because of the nature of the database. It was assumed that all patients received best medical treatment (BMT) prescribed at the discretion of the physician.

Costs of PAD treatment

A Fontaine classification by a vascular surgeon is always required for billing purposes in the Dutch healthcare

Table 2. Revascularizations per group per anatomical section.

		Primary treatment		Secondary treatment	
		INT - group	SET - group	INT - group	REST - group
Patients with intervention (n - %)		1363 (100%)	45 (6.4%)	480 (35.2%)	132 (4.6%)
Interventions per section					
Invoices of Radiology dept.	Bypass revascularization	8	2	8	2
	Ao-II, (one sided)	477	20	193	69
	Ao-II, (both sides)	219	5	94	19
	FemPop (one sided)	313	17	147	47
	FemPop (both sides)	27	1	14	6
	Crural (one sided)	12	0	8	1
Invoices of Surgery dept.	Endovascular ^a	9	0	0	0
	Open	289	2	16	0
	Open (both sides)	19	0	0	0

Ao-II = aorto-iliac; FemPop = femoral-popliteal.

^a Unspecified because of suboptimal registration.

system. All claudication related invoices (by physician and physiotherapists) for primary as well as secondary treatment within 2 years follow-up of t_0 were screened. The majority of interventions in 2009 were performed by radiologists, based on referral by vascular surgeons. Total costs generated in the SET, INT, and REST groups were calculated by adding all intervention costs for the group to which the patient was initially allocated. Discrimination between a secondary ipsilateral intervention and a primary contralateral intervention was not possible because of the nature of the database, aimed at costs registration. Mean total costs (MTC) per patient per group were calculated. Expenditures for medication use were not incorporated into the calculations.

Sensitivity-analysis of the REST group

Patients in the REST group were supposed to have received walking advice. When a patient is referred to a vascular surgeon for IC by a GP, a "PAD Fontaine 2" (synonymous to IC) invoice is registered. However, if IC is subsequently ruled out, the invoice is often not corrected to the proper invoice "ruling out IC". In a prospective analysis of 100 consecutive patients, it was found that 30% of the GP referrals with presumed IC in fact received an alternative, non-IC diagnosis (unpublished results). This phenomenon is not financially driven as reimbursement of a "rule out" invoice appears €1.43 higher. This incorrect assignment may have contaminated the composition of the REST group so it was decided to exclude the REST group from the SCM cost-analysis. However, a cost-analysis of the REST group was performed in an additional sensitivity analysis (SA), assuming 30% non-IC patients.

Cost-analysis of nationwide adherence to a SCM

The costs of SCM were estimated for patients in the SET and INT groups. Successful treatment guided by a SCM depends on two critical success factors:

1. surgeon compliance (willingness) to refer each IC patient to SET. Despite the fact that, according to contemporary international guidelines, all patients with

Table 3. SET sessions per group.

		Primary treatment		Secondary treatment	
		SET - group	INT - group	SET - group	REST - group
Patients with SET	(<i>n</i> - %)	701 (100%)	NR	141 (10.3%)	299 (10.3%)
Number of SET sessions	(mean ± SD) (min–max)	48 (±42) (1–271)	NR	38 (±35) (1–176)	42 (±47) (1–470)

NR = not relevant.

IC initially should be referred for SET,^{2–4} this ratio was hypothetically set to 80% (best), 50% (moderate), and 30% (worst) based on reimbursement issues, appreciation of SET by vascular surgeons, and preference (although evidence to do so is lacking) for revascularization in certain cases.

- patient motivation to participate in a SET program, which largely depends on reimbursement issues (level of compensation by the insurance company) as well as a thorough understanding of the benefits of a SET program in comparison with an invasive intervention. The latter is also strongly associated with the surgeon's knowledge regarding SET and the willingness to refer. To allow for variation in patients' willingness, this ratio was arbitrarily set at 80% in case of full reimbursement for all IC patients and optimal provision of information. At the other end, 25% was chosen for the current levels of reimbursement and information provision. These ratios were also suggested from the results of a questionnaire completed by a cohort of Dutch vascular surgeons.⁹

Combining doctor and patient factors in a comparative model resulted in six hypothetical scenarios (80%–80%, 80%–25%, 50%–80%, 50%–25%, 30%–80%, and 30%–25%). As both factors are interrelated (physicians will limit SET referrals if patients drop out as a result of reimbursement issues; conversely, physicians may not refer to SET because of presumed preference for an intervention), only the three most likely scenarios were considered: best (80%–80%), moderate (50%–80%), and worst cases (30%–25%). In addition, extrapolation for the Dutch population was performed by multiplying total savings in the total group by a factor of 4.94 (21% of the Dutch population is insured by CZ).

Data analysis

The insurance database was analyzed with SAS (SAS Institute Inc, New York, USA). Differences between categorical variables were analyzed using a chi-square test. Statistical analyses were performed using SPSS 20 software (SPSS Inc, Chicago, USA). A two-sided $p < .05$ was considered statistically significant. Calculations of costs were made using Excel 2011 (Microsoft Office, Redmond, USA). Graphs were created with Graphpad Prism 5 (GraphPad Software Inc, La Jolla, USA).

RESULTS

Adherence to a SCM

A total of 5,824 patients with "PAD Fontaine 2" (IC) were identified, of which 871 patients were excluded for reasons

listed in Fig. 1, leaving 4,954 IC patients for analysis. Fourteen percent received SET, whereas 28% were primarily treated with an invasive intervention (INT). The remaining 58% ($n = 2,890$) did not receive any of these two treatment regimens within 3 months of diagnosis (REST). Patient characteristics of the three groups are shown in Table 1. Significant differences between groups were found with respect to age, gender, and congestive heart failure. Patients in the INT group were younger, more often male, and had congestive heart failure less often.

Primary and secondary treatments are depicted in Tables 2 and 3. A total of 45 SET patients (6.4%) were secondarily treated with an endovascular ($n = 43$) or open surgical ($n = 2$) procedure (Table 2). In 1,363 INT patients, 1,055 endovascular (aortoiliac lesions: 696; femoropopliteal lesions: 340) and 308 open surgical procedures were performed initially (Table 2). In 480 of these patients (35.2%), an additional revascularization procedure (endovascular: $n = 464$; open: $n = 16$) was performed within 2 years. In the REST group, 299 patients (10.3%) were additionally treated with SET and 132 patients (144 interventions, 4.6%) with an endovascular revascularization.

Costs of IC treatment

A wide range of costs was found regarding the physician-based invoices. Bills ranged from minimums of €99 and €2,515, to maximums of €14,428 and €50,173 for the SET and INT groups, respectively. Total costs ranged from a single visit at the patient outpatient clinic (€99) to a bilateral open surgical revascularization. Mean costs of SET declarations ranged from €28 to €7,187 in the SET group to a maximum of €12,886 in the REST group as related to the number of SET sessions (1 to 470 sessions; Table 3). The MTC per patient in the SET group (€2,191) was almost five times lower than a patient in the INT group (€9,851; Table 4).

Table 4. Mean total costs per patient per group during 2 years of follow-up.

	Group		
	SET Mean (min–max)	INT Mean (min–max)	REST Mean (min–max)
Physician based invoices (€)	890 (99–14,428)	9,745 (2,515–50,173)	705 (99–17,935)
Physiotherapist based invoices (€)	1,301 (28–7,187)	106 (28–4,914)	118 (28–12,886)
Mean total costs (MTC)	€ 2,191	€ 9,851	€ 824

Table 5. Implementation of a stepped care model.

Scenario	Groups		Costs	Savings			Sensitivity analysis			
	SET (n)	INT (n)		Cost-analysis INT to SET ^a	Dutch population	Group SET (n)	REST (n)	REST to SET ^a	(INT to SET) + (REST to SET) ^a	Dutch population
Current (14% - NR%)	701	1,363	€ 14,953,716	NR	NR	701	2023	NR	NR	NR
Best case (80%–80%)	1,573	491	€ 8,276,594	€ 6,677,121	€ 32,992,834	1996	728	–€ 1,770,685	€ 4,906,436	€ 24,237,794
Moderate case (50%–80%)	1,246	818	€ 10,780,515	€ 4,173,201	€ 20,620,521	1510	1214	–€ 1,106,678	€ 3,066,523	€ 15,148,624
Worst case (30%–25%)	803	1261	€ 14,171,240	€ 782,475	€ 3,866,348	853	1871	–€ 207,502	€ 574,973	€ 2,840,367

NR = not relevant.

^a Based on CZ population.

Cost-analysis of a hypothetical nationwide adherence to a SCM

The effects on cost-savings of SCM with and without sensitivity analysis (SA) are shown in Table 5. In the 2009 situation (14% SCM), the costs were 17.3 million euros. In the hypothetical best-case scenario (80%–80%), 1,573 of the 2,064 eligible patients would receive SET and 491 a vascular intervention as initial treatment. Nationwide implementation of such an 80%–80% SCM scenario would result in annual savings of 33.0 million euros for the Dutch population (Table 5). Implementation of the worst-case scenario (30%–25%) would still reduce the yearly costs of IC treatment by 3.9 million euros (Table 5). In the sensitivity-analysis (SA), 2,023 of 2,890 patients remained in the REST group (30% non-PAD exclusion), leaving 4,087 eligible IC patients for analysis. In the best-case scenario, 2,868 of these patients would receive SET, 491 a vascular intervention and 728 walking advice. Savings would still be reduced from 33.0 to 24.2 million with an 80%–80% SCM implementation after SA (Table 5).

DISCUSSION

Three international guidelines recommend SET as a first line treatment for patients with IC,^{2–4} supported by cost-effectiveness analyses.^{13,16–20} Unfortunately, the availability of SET programs in Europe is poor.^{10,21} Some consider the substantial investment to achieve nationwide implementation of SET programs as a problem.¹³ These findings imply that the initial investments to increase the availability of SET in other countries may be beneficial when guidelines and therefore the SCM are followed. Despite the Dutch having a well-organized community based SET network, this should not be an excuse for other European countries but a motivation to implement such a network. Furthermore, SCM implementation effects and thus cost-savings may even be larger as most foreign healthcare systems have low penetration of (community-based) SET programs and thus a potential lower threshold for invasive vascular interventions. Moreover, the calculated savings of a SCM approach in this study are in euros, while a reduction of morbidity and mortality ratios might occur as well.

Makris et al. claimed a 100% SET availability in the Netherlands in 2012.¹⁰ The present study demonstrated that a mere 14% of the IC patients were actually referred for SET in 2009. The discrepancy between a relatively low percentage of SET referrals and high availability of SET programs might be explained by the combination of conflicting reimbursement issues, increased patients' and physicians' enthusiasm for interventional procedures,¹⁶ and a lack of appreciation of SET.⁹ The latter might be caused by ambiguities in contemporary guidelines, which may be responsible for invasive procedures being used too liberally for IC caused by aortoiliac lesions as stated in the TASC.⁴ In contrast, the NICE guideline suggests initial treatment of this type of lesion with SET.³ Several large trials show inconclusive results concerning treatment of aortoiliac lesions.^{22–25} In the present study, 28% of the patients received a primary revascularization, of which 51% involved aortoiliac lesions. More than half (58%) of the included patients were assumed to have received walking advice. The present study therefore clearly demonstrates that the TASC II/NICE guidelines (restricting interventions to patients not responding to SET) are largely neglected in Dutch practice. A nationwide implementation of a SCM might tackle these issues, and the anticipated cost-savings presented in this study may facilitate current conflicting issues in reimbursement.

Moreover, SCM may have substantial influence on IC patients' individual treatment strategy. It is known that patients suffering from IC, regardless of the severity of the walking restriction, have a range of other limitations.²⁶ Initiating treatment with SET may provide awareness of important functional restrictions in daily life other than those caused by IC (e.g. COPD, congestive heart failure, osteoarthritis, spinal stenosis, equilibrium disorders). So following a SCM may prevent potentially futile vascular interventions in multi-morbid patients who are limited by more than just IC. Furthermore, once (successful) invasive treatment has been performed, recurrent ipsilateral or newly developed contralateral obstructions are likely to be treated by invasive means too, contributing to a high re-intervention ratio (35%) in the INT group. Surprisingly, this was also found by others¹⁶ and is in line with reported

patency rates of endovascular revascularizations.^{27,28} Additionally, initiating a SET first policy might not meet the aspirations of the contemporary articulate and demanding patient, focused on a quick fix for the problem. The present findings suggest that a SCM, with a 3-month trial period preceding invasive treatment, in which patients not responding to SET are eligible for invasive treatment, might decrease the number of interventions.

This study has limitations inherent to its retrospective character. Some might argue that selection bias may have influenced the results, as patients with more severe IC complaints or with a specific atherosclerotic lesion may preferentially have been treated by invasive means. However, all included patients had IC classified as Fontaine II, and according to contemporary guidelines should have received SET as a primary treatment.^{2–4} In addition, a correcting factor was applied, in that the (best-case scenario) calculations referral rate was set at an 80% ratio (instead of the guidelines' 100%), permitting the remaining 20% to be treated based on the personal preference of the patient or vascular surgeon.

Furthermore, this study showed differences in patient characteristics between groups (age, gender, and CHF). Unfortunately, it was not possible to adjust the analyses for these covariates because of privacy limitations of the insurance company database. The findings reveal that young males were treated more frequently by revascularization compared with older patients or females. This phenomenon might reflect assumptions and indirect evidence suggesting that invasive treatment should be preferred in a working age population as recovery is deemed quicker. The same might be the case in the assumption that as endovascular treatment for aortoiliac lesions is more durable compared with femoropopliteal lesions, this warrants an intervention in aortoiliac lesions.²⁷ However, as far as the authors know, no evidence substantiates such an invasive first line treatment for certain IC subgroups.

A formal cost-effectiveness study could not be performed as the insurance company's database lacks data on treatment effect or outcome. Furthermore, costs related to an intervention of the ipsi- or contralateral leg could not be identified which may have biased total costs of the INT group. However, this limitation is relative as walking exercise pertains to both legs.

Future perspectives

Reimbursement issues in the Dutch healthcare system remain an issue. Optimization of a SCM depends on political decision-making and awareness of the functional and financial advantages of SET by healthcare insurers. The impact of a SCM implementation on Dutch as well as European society should be subject to future research.

CONCLUSION

In addition to the solid evidence supporting SET as first line treatment for patients with IC, introduction of and

adherence to a SCM may lead to significant savings of healthcare resources associated with the treatment of patients with IC.

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None.

CONFLICT OF INTEREST

None.

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