

Reduction of amputation rates in multidisciplinary foot clinics — a systematic review

Quinlivan E, Jones S, Causby R & Brown D

ABSTRACT

The multifactorial and complex nature of diabetes and vascular diseases in lower limb complications has led to the development of multidisciplinary foot clinics (MDFCs), in which a team of various health professionals work together to achieve the best outcome for the patient. While previous studies have evaluated the effectiveness of such interventions, no study has collated their findings to determine if this method of service delivery is appropriate. Therefore, the aim of the current study was to determine if MDFCs significantly reduce amputation rates compared to standard methods of service delivery. A systematic literature search was undertaken in early 2010 to find articles evaluating the effectiveness of MDFCs in reducing amputation rates. Specific inclusion and exclusion criteria were applied to find the most appropriate literature and the articles were then assessed for methodological bias. Seven articles were included in the final review using these criteria. A statistically significant decrease in amputation rates following the implementation of an MDFC was reported in five out of the seven studies. Although all scored favourably in the critical appraisal of bias, there are large flaws in the methodological designs of these studies. The literature does suggest there is a great advantage to using MDFCs to decrease amputation rates in high-risk patients. However, without strong literature to back up this delivery approach, it cannot be regarded as evidence-based. Thus, further study must be performed, focusing on improving research protocols to achieve strong evidence to consolidate the use of MDFCs.

Keywords: multidisciplinary foot clinic, high risk.

Elysia Quinlivan *

Bachelor of Podiatry with First Class Honours
ejquinlivan@gmail.com
Tel 0402 787 511

Dr Sara Jones

PhD, MSc, BA, DipAppSci(Pod)
Bachelor of Podiatry Program Director, School of Health
Sciences, University of South Australia, North Terrace,
Adelaide, SA 5000, Australia

Ryan Causby

BAppSc(Pod), GradDip(Pod)
School of Health Sciences, University of South Australia,
North Terrace, Adelaide, SA 5000, Australia

Diana Brown

BAppSci(Pod), MPod
Podiatry Manager, The Queen Elizabeth Hospital,
Woodville Road, Woodville, SA 5011, Australia

*Corresponding author

INTRODUCTION

Approximately 85 per cent of amputations in people suffering from diabetes mellitus are preceded by a foot ulcer^{1,2}. It has been estimated that a lower limb is amputated due to diabetes every 30 seconds^{3,4}. Lower extremity amputations are a highly debilitating complication of diabetes and have a huge physical, social and emotional impact on the patient and their family, while also placing a significant burden on the health care system⁵⁻⁷. In Australia, 2629 amputations were reported between 1995 and 1998, representing 13.97 amputations per 100, 000 people in the total population⁸. It is projected that this level will rise further.

The aetiology of diabetic foot ulceration is multifactorial, involving both intrinsic and extrinsic factors¹⁰. Intrinsic risk factors include age, duration of diabetes, decreased immune response and the presence of neuropathy, vascular disease or structural deformity¹⁰. Extrinsic risk factors include the health status of the patient, smoking, social factors and any injury to the lower limb (trauma, burn, chemical)¹⁰. These are described in more depth in Table 1.

The three leading risk factors for ulceration are neuropathy, vascular disease and a compromised immune system, often in conjunction with injury or trauma to the foot¹⁰. Sensory neuropathy can lead to injuries remaining unnoticed due to a lack of pain and pressure feedback¹⁰. This may lead to a delay in appropriate wound management and

Table 1: Risk factors of ulceration those with diabetes

Intrinsic	Extrinsic
Neuropathy <ul style="list-style-type: none"> Sensory Motor Autonomic 	Trauma <ul style="list-style-type: none"> High impact Constant repeated low pressure
Vascular disease <ul style="list-style-type: none"> Microvascular Macrovascular 	Thermal <ul style="list-style-type: none"> Burns Cold injury
Decreased immune response	Chemical
Structural deformity	Smoking
Age	Living alone
Duration of diabetes	Decreased knowledge/self-care
Previous amputation	Occupation
Nephropathy	Fitness
Retinopathy	Obesity
History of amputation	Footwear
History of ulceration	Poor glucose control

Adapted from Frykberg (1997) and compiled with the works of Williams, Manias & Walker (2010), Saudek & Brick (2009), Frykberg (1998), Armstrong, Lavery & Harkless (1996).

coupled with a decreased immune status in individuals with diabetes, can increase the likelihood of infection¹⁰. Similarly, a decrease in vascular supply to the lower limb will reduce the flow of nutrients and oxygen and increase the build-up of waste products at the wound site, further delaying healing capacity¹⁰.

Podiatry management of the diabetic foot has an underlying focus on preventive screening, education and management. This will commonly include regular examination of the feet for injury; vascular, neurological and other objective screening (that is, dermatological); education of patients and family members; and identification of appropriate footwear¹¹. However, the need to address and actively manage other factors such as metabolic status, malnutrition, oedema, infection and ischaemia requires the involvement of disciplines other than podiatry in the treatment strategy of complex foot presentations¹². Therefore, multidisciplinary foot clinics (MDFCs) have developed in response to the need for an improved method of service delivery from this group of practitioners collaborating together for patient management.

MDFCs were first established in the United Kingdom in the 1980s, providing regular debridement of pressure areas and wounds, treatment of infection, custom-made footwear and patient education¹³.

A variable number of disciplines may be involved in the treatment and management of patients in MDFCs. The disciplines most commonly included are: podiatrists, vascular surgeons, endocrinologists, infectious disease specialists, diabetes nurse educators and wound

care nurses¹⁰. Additional to this, disciplines such as orthotists, physiotherapists and psychologists have been described in the literature^{10,14}. Edmonds (2006) identified five stages of diabetic foot pathology and how the multidisciplinary team is involved in each of the stages¹⁴.

In previous literature, several articles have stated that MDFCs are known to reduce amputation rates in those with diabetes¹⁵⁻²⁷. However, no systematic reviews have been previously undertaken to evaluate the strengths and weaknesses of these publications and their underlying research design. Therefore, the aim of the current study was to undertake a systematic review of the literature to determine if multidisciplinary foot clinics are more successful in significantly reducing amputation rates.

METHOD

Research or PICO question

A PICO question is essentially described as a “population-intervention-comparator-outcome”²⁸ question which identifies specific groups for the comparison of results in various interventions. Thus, the research question in this systematic literature review was: Do multidisciplinary foot clinics significantly reduce lower limb amputation rates?

Search strategy

A systematic search of the literature was undertaken from February to March 2010 to identify publications relating to the effectiveness of MDFCs reducing lower extremity amputations.

Article selection strategy

Published studies of various methodological designs were obtained via searching of electronic databases. The databases searched were CINAHL, Cochrane, EMBASE and Medline. Articles must be available in full-text and in the English Language. The full list of search dates, limitations and search terms used are listed in Table 2.

Article eligibility was screened on title and abstract basis. If the content of the article remained unclear, the full text was also screened. Full-text documents were accessed via both online and hard copy journals.

For studies to be included in the review, articles had to meet the following criteria:

- They were undertaken in a multidisciplinary foot clinic or similar setting.
- The amputation rate was used as the outcome measure.
- Interventions took place in an outpatient setting.
- They were written in the English language.

Studies were excluded if:

- Interventions used were primarily surgically based, such as limb salvage units.
- Interventions focused primarily on education.
- Outcome measures focused only on health cost analysis or variables other than amputation rate.

Table 2: Systematic literature review search strategy

Database	Date	Search terms								
CINAHL -Academic Search Premier -CINAHL -E-journals -Health Source: Nursing/ -Academic Edition	10/02/2010	multidisciplin* OR interdisciplin* OR care team OR MDFC	AND	Clinic OR foot care clinic OR care team	AND	Foot OR high risk OR diabetes OR diabet* OR peripheral vascular disease	AND	Amputation* AND incidence OR LEA	AND	decreas* OR reduc* OR declin*
Cochrane	11/02/2010	multidisciplin* OR interdisciplin*	AND	Clinic OR team	AND	Foot OR high risk OR approach	AND	Amputation* AND incidence	AND	reduc* OR decreas*
Embase -AMED (Allied and Complementary Medicine) 1985 to February 2010 -EMBASE 1980 to 2010 Week 08	28/02/2010	multidisciplin* OR interdisciplin*	AND	Clinic OR team	AND	Foot OR high risk	AND	Amputation* AND incidence	AND	reduc* OR decreas*
Medline -Ovid MEDLINE(R) 1950 to February Week 3 2010	01/03/2010	multidisciplin* OR interdisciplin* OR interdisciplinary communication OR outpatient clinic OR hospital	AND	Clinic OR patient care team	AND	Foot OR feet OR high risk	AND	Amputation* AND incidence	AND	reduc* OR decreas*

- Were set in an inpatient setting.
- Not available in English.
- Clinical setting focused on prevention.

No limits were applied on the year of publication or geographical location. Following the retrieval of all included full-text articles, article reference lists were searched for the possibility of other relevant articles

Assessment of methodological quality

The LOW critical appraisal tool has nine questions and each question has different criteria. These criteria assesses areas including the methodological rigour of the studies, validity and reliability of subject recruitment and data collection, power analysis and whether

confounding variables had been accounted for. Each article was assessed on these criteria and each section was graded as either a 'Yes', 'No' or 'Can't tell'. A 'Yes' response was given one point for the question while a 'No' or 'Can't tell' response was given zero points. The total points were added up to give a score out of nine²⁸. The critical appraisal tool is presented in Table 3.

The articles retained were assessed for methodological quality using the 'LOW' critical appraisal tool custom designed by Lewis, Williams and Olds for a systematic literature review²⁸. This critical appraisal tool was deemed appropriate for this particular review as it can be applied to a large number of different methodological designs and is not limited by the article's position in the hierarchy of evidence, as developed by the National Health and Medical Research Council²⁹. Each article was appraised by two independent reviewers (EQ

Table 3: Lewis, Olds, Williams (LOW) critical appraisal tool

1. Did the study address a clearly focused issue?	Yes
• The population studied	No
• The intervention/outcome studied	Can't tell
• Whether the study tried to detect a beneficial or harmful effect	
2. Were the participants recruited in an acceptable way?	Yes
• Were the eligibility criteria specified so that the participant recruitment could be repeated?	No
• Were the participants representative of a defined population?	Can't tell
• How likely was the recruitment process to introduce bias? (Participants likely to respond positively or negatively to intervention)	
3. Was there a sufficient number of participants selected?	Yes
• Was there a power calculation?	No
• Did the authors provide any justification for the sample size?	Can't tell
4. Was there a separate control group?	Yes (go to 5)
	No (go to 6)
5. Separate control group:	Yes
• Was there equal chance of participants being allocated into either group?	No
• Were the controls representative of the intervention group (similar age, gender and other variables other than the variable of interest)?	Can't tell
• Were the eligibility criteria specified so that recruitment of the controls could be repeated?	
• Was there a sufficient number of controls selected?	
Go to 7	
6. Baseline measures for participants acting as their own controls:	Yes
Where appropriate:	No
• Was the baseline stable? (How confident are you that the pre measures were stable, was there a run-in period?)	Can't tell
• Was the order of interventions randomised?	
• Was the washout period between intervention/control acceptable?	
7. Were the outcomes measured accurately to minimise bias?	Yes
• Are there references to support the use of outcome measures? (Details, reliability and validity of measures)	No
• Were the measurement method similar/the same in participants and controls?	Can't tell
8. Have the confounding factors been accounted for?	Yes
• Do the authors state potential for confounding variables?	No
• Do the authors discuss and refute the impact of potential confounding variables?	Can't tell
• Have the authors taken account of the potential confounding factors in the design, results and/or in the analyses?	
9. Results	Yes
a. Were the results presented so the effect size was shown or could be calculated?	No
• Are mean/SD (or the raw data) available to allow calculation of effect size?	Can't tell
• Size of the p value	
• Size of the confidence intervals	
• Are data for participant attrition/withdrawal present?	
b. Do you subjectively believe the results?	
• NOT do you accept the results?	Yes
• What are the bottom line results?	No
• Was the analysis appropriate to the design?	Can't tell
Final score	/9
Yes=1, No=0, Can't tell=0	

and DB). Any discrepancies in scores were discussed to see if the differences could be resolved to assess inter-rater reliability. The LOW scale, however, has not been tested for validity other than its use in the study performed by Lewis, Williams and Olds²⁸.

RESULTS

The article search in the databases provided a total of 3248 articles. After screening of the titles and abstracts, 182 studies remained of interest. After duplicates were removed, 67 full-text articles were obtained via electronic and hard copy journals. The reference lists of each of the articles were explored and a further 12 articles were identified and hard copies gathered. The full texts of the articles were evaluated following the above inclusion/exclusion criteria. Seven studies were retained for the systematic review. An overview of the article search and selection process is presented in Figure 1:

All identified studies were either a retrospective or prospective study design, ranking equally as Level III-2 on the NHMRC hierarchy of evidence²⁹.

Critical appraisal of bias

The results of the critical appraisal of bias showed that all the included studies scored with a minimum of five out of nine and a maximum of seven out of nine. The individual breakdown for the scores per criteria and shown in Table 4.

It was reported there was a statistically significant decrease in amputation rates in five out of the seven studies. In the study by Dargis *et al.* there was a decrease in amputation rates; however, there was not a statistically significant difference¹⁶. In the final study by Van Gils *et al.*, the amputation rate for the population was reported and compared to previous studies of similar populations but no calculations were provided to support these claims²⁷. As such, the presence of a statistically significant decrease and percentage decrease

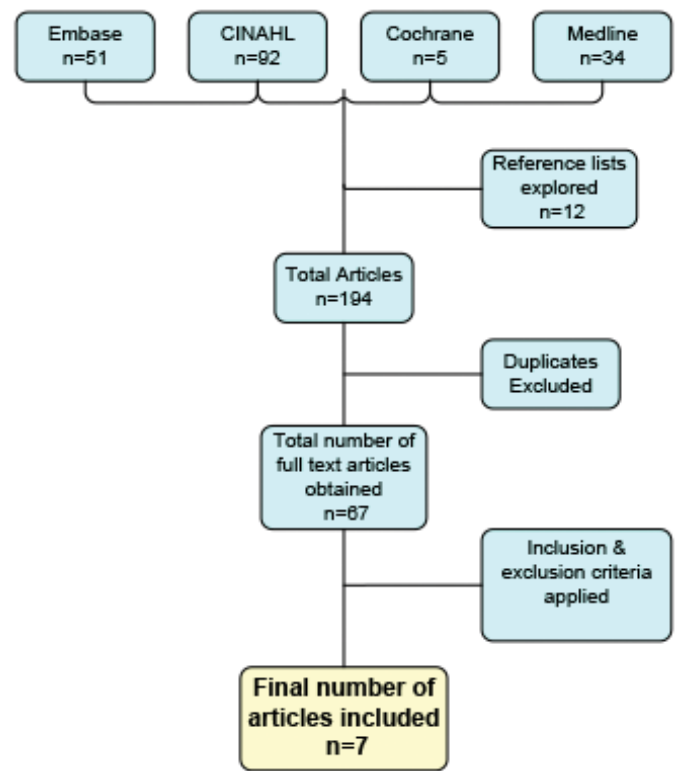


Figure 1: Systematic literature review article selection process

in amputation rate could not be reported for this study. A summary of the key features of the articles included in the systematic literature review is presented in Table 5.

DISCUSSION

It was found that five out of the seven articles reported a statistically significant reduction in amputation rates when using

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Table 4: LOW scores per article

Author	Answer per question (Q)									Total score /9
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	
Van Gils <i>et al.</i> 1999	Y	Y	N	N		CT	CT	Y	Y, Y	6
Dargis <i>et al.</i> 1999	Y	Y	N	Y	CT		Y	Y	Y, Y	7
Meltzer <i>et al.</i> 2002	Y	Y	N	N		Y	CT	N	Y, Y	5
Schraer <i>et al.</i> 2003	Y	Y	N	N		Y	CT	Y	Y, Y	6
Anichini <i>et al.</i> 2007	Y	Y	N	N		CT	Y	N	CT, Y	5
Rerkasem <i>et al.</i> 2007	Y	Y	CT	Y	CT		CT	Y	N, Y	5
Rerkasem <i>et al.</i> 2008	Y	Y	CT	Y	CT		CT	Y	N, Y	5

Where: Yes=Y=1, No=N=0, Can't tell=CT=0

an MDFC treatment approach compared to standard treatment approaches^{15,21,23,24,26}. However, the quality of the articles must be explored to determine with what level of confidence we are able to believe the evidence reported. This has been assessed using the LOW critical appraisal tool.

All of the articles met the criteria for sections one and two. For section one all studies were identified as addressing a clearly focused issue, identifying the appropriate population and the reasoning behind the studies. Participant recruitment was explored in section two and all included studies listed eligibility criteria and the potential for bias in the recruitment selection.

None of the articles included a sufficient number of participants. None of the studies described a power calculation to determine if a sufficient number of participants were involved in the study nor did they attempt to justify the number of participants included.

A separate control group was only used in three studies^{16,23,24}. Of these three, Dargis *et al.* was the only study to compare the MDFC treatment with a concurrent control group receiving 'standard' treatment at the same time¹⁶. However, subjects in this study were not randomised into control or trial groups. Instead, patients attending the clinic at Kaunas formed the trial group after implementation of an MDFC, while patients attending clinics in hospitals in other geographical areas of Lithuania formed the control group. One would anticipate that this could potentially increase bias, due to the possibility of influence of regional factors in the results. This study did report that the characteristics of the populations were similar at baseline, potentially controlling the presence of confounding variables; however, geographical, social and socio-economic factors were not addressed. The other two studies that utilised control groups, both by Rerkasem *et al.* in 2007 and 2008, compared the intervention groups to the outcomes of standard care in previous (earlier) time frames^{23,24}. This may have introduced a number of confounding variables influencing the accuracy of the results, such as the introduction and use of more recent advances in technology or knowledge in the areas of wound dressings and revascularisation. This method does rule out some ethical concerns that could be otherwise

present in potentially refusing higher levels of care to those within the control group. However, this argument for the study design was not utilised in the articles and the authors did not address this matter as a potential confounding factor.

All studies that utilised a separate control group received a 'Can't tell' result for section five of the critical appraisal tool^{16,23,24}. For those studies with a separate control group, it was difficult to determine if they had successfully implemented this design. As discussed previously, there was not an equal chance for the subjects to be allocated to both the trial or control groups and the eligibility criteria were not discussed in detail regarding selection into the control group. All studies reported that there were no statistically significant differences between the characteristics of the groups at baseline.

Of the remaining four studies which did not utilise a separate control group^{15,21,26,27}, three^{15,21,26} used the same subjects for baseline controls and results after intervention and one did not utilise a control group at all. Van Gils *et al.* did not utilise a control group, rather comparing results from an MDFC to previous literature to determine if the reduction in amputation rate was similar to those previously reported²⁷. The remaining three studies utilised the same subjects as baseline controls. However, it was difficult to determine the methodology as this was not explicitly stated by the authors. For example, the study by Meltzer *et al.* reported that "retrospective medical chart review was performed in two phases: before (control) and 18 months after (test period) implementation of a systematic multidisciplinary team approach"²¹. This does not specifically identify if the same subjects were used in the control and test periods. Schraer *et al.*²⁶ and Meltzer *et al.*²¹ used an appropriate method for using the same subjects as baseline; however, it was unable to be determined if Van Gils *et al.*²⁷ and Anichini *et al.*¹⁵ had used appropriate methods. Both Schraer *et al.*²⁶ and Meltzer *et al.*²¹ had a washout period between the control and intervention periods. Anichini *et al.*¹⁵ reported results from the start and end of the introduction of the clinic and thus were determined not to have had a washout period, while Van Gils *et al.*²⁷ followed patients for some time after the initial trial period and were also determined not to have had an adequate washout period.

Table 5: Key characteristics of studies included in systematic literature review

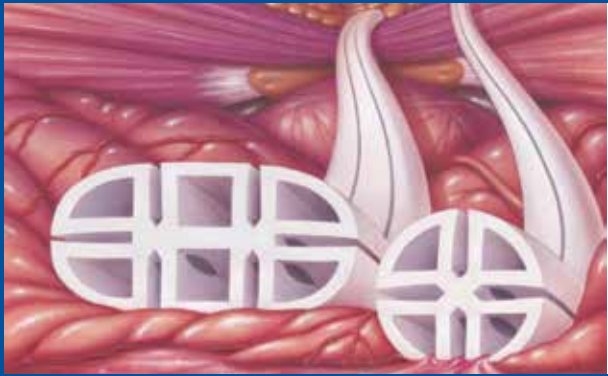
Author	Data collection method	Total number of participants	Results	
			Significant decrease in amputation rate	LOW score /9
Van Gils <i>et al.</i> 1999	Computerised database search and medical record review	124	Not reported	6
Dargis <i>et al.</i> 1999	Medical record review and manual testing	145	No	7
Meltzer <i>et al.</i> 2002	Medical record review	234	Yes	5
Schraer <i>et al.</i> 2003	Medical record search of patient registry and computerised databases at medical centres	10 134.5	Yes	6
Anichini <i>et al.</i> 2007	Medical record review	1965	Yes	5
Rerkasem <i>et al.</i> 2007	Medical record review & current treatment	171	Yes	5
Rerkasem <i>et al.</i> 2008	Medical record review & current treatment	183	Yes	5

It was determined only two studies^{15,16} measured outcomes accurately to minimise bias, whilst it could not be determined if this was the case in the other studies. These studies did not provide adequate references to support their choice of statistical methods used to measure outcomes. Dargis *et al.* was one of the few articles to go into detail and report confidence intervals, odds ratios and chi-squared results¹⁶. It was, however, along with all the other articles, still lacking in details of reliability and validity.

Confounding variables and their influence on the results were discussed in five of the seven articles^{16,23,24,27}. Van Gils *et al.* raised a valid point that treatment provided to patients within an MDFC

varied and was not standardised²⁷. Due to the varied nature of the conditions involved in such clinics and the different associated co-morbidities, multidisciplinary care is not able to be standardised but rather varies from case to case, based on the clinical judgement of the clinicians. Rerkasem *et al.* expressed the opinion that using a historical cohort was not ideal in terms of rigour and adding value to the findings, suggesting a randomised controlled trial should be pursued before such a clinical change is implemented worldwide²³. Both Meltzer *et al.* and Anichini *et al.* failed to discuss the possibility of any influencing variables and were, therefore, given a score of zero for this section^{15,21}.

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The final section of the critical appraisal tools looked at two sections — the statistical power of the results and the believability of the results. Only four studies^{16,21,26,27} presented the results in a manner that meant the effect size could be calculated, which involved describing statistics such as size of p-values and confidence intervals, withdrawal rates and listing the mean/standard deviation or raw data to be able to calculate the effect size. All articles were deemed to have believable results.

CONCLUSION

A decrease in amputation rates after implementation of MDFCs was reported across all studies included in the systematic literature review; however, only five out of the seven included articles reported a statistically significant decrease. Although all the articles scored quite favourably in the critical appraisal of bias, there were some large flaws in the methodological designs of these studies. The literature does point towards a great advantage of using such clinics to decrease the level of amputation; however, without strong literature to back up the use of this intervention, evidence-based practice cannot be brought into place. Thus, further study must be carried out in this area, focusing on improving the research protocols to achieve this strong evidence to back up the use of clinics.

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