Original Article

A review of amputation and revascularisation rates in a small European state

Matthew Grima, Ian Said, John Duncan, Kevin Cassar

Abstract

Background: Until 2007 vascular services in Malta were provided by general surgeons with a vascular interest. In late 2007 a vascular specialist was recruited to contribute to the service. This catered for a gradual transfer of services to a pure vascular specialist service in 2014.

The aim was to assess the impact of the introduction of vascular specialist services on lower limb major and minor amputation rates and open revascularisation procedures in Malta.

Methods: This is a retrospective analysis of prospectively collected data. Data from the Hospital annual surgical operation reports and the Vascular Database was analysed between 2002 and 2014. Data was analysed by time period (Period 1: 2002-2007 – no vascular specialist service; Period 2: 2008-2013 - partial vascular specialist service; Period 3 – January to December 2014 complete vascular specialist service).

Results: There was a significant drop in the average rate of major amputations/year between Period 1 and Period 2 (120 vs 96; *p=0.008*) and between Period 1 and Period 3 (120 vs 64; *p<0.001*). A significant increase in minor amputations/year between period 1 and period 2 (102 vs 242; p<0.001) and between period 1 and period 3 (102 vs 449; *p<0.001*) was noted. There was significant increase in open revascularisation rates between period 1 and period 2 (21.5 vs 73.2; *p<0.001*) and between period 1 and period 3 (21.5 vs 144; *p<0.001*).

Conclusion: The employment of vascular specialists can lead to a significant increase in lower limb open revascularisation rates and a concomitant significant reduction in lower limb major amputation rates.

Key words

limb salvage, amputations, blood vessel prosthesis implantation, diabetic angiopathies, peripheral vascular diseases

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Introduction

The availability of specialised vascular services has increased dramatically over the last decades throughout Europe and around the world. There are however many areas where patients with vascular problems are still treated by general surgeons with or without a vascular interest. This may be due to limited financial or human resources and occasionally because of geographical isolation and logistics. It is generally agreed that patients with vascular problems treated by vascular specialists have better outcomes. It has been shown that in parts of the United States, the supply of more vascular specialists resulted in an increase in the rate of major bypass procedures and a reduction in lower limb amputations.[1] Indeed significant regional variations exist in major amputation rates even within the same country as shown in a study from the United Kingdom[2] which could be in part explained by the different access to vascular

services. In other countries differences in outcomes have been related to socioeconomic groups [3-4] or ethnicity[5] which may in turn be related to the level of access to specialised vascular care.

The impact of revascularisation on major amputation rates has been debated and evidence has been conflicting with some publications reporting a correlation between revascularisation rates and amputation rates[6] while others have failed to demonstrate any clear correlation.[7-8]

Malta is an island state in the Mediterranean, an EU member state since 2004 with a population of 417,432.[9] There is one major referral hospital, St Luke's Hospital which migrated to Mater Dei Hospital, Msida in October 2007. Malta has a national health service which is free at point of care with all services from primary to tertiary care being free and funded by central government. The hospital provides both acute and elective vascular care for the whole country.

The prevalence of diabetes in Malta was reported as 10% of the population in 2005[10] which is one of the highest in Europe. The World Health Organisation estimated that the total number of diabetics in Malta in 2000 was 39,000 and predicts that by 2030 this figure will reach 57,000.[11] The 2005 census had estimated the national population to be 404,962 while in the previous census held in 1995 this was 378,132. No census was held in 2000 but the estimated population in the year 2000 based on the 1995 and 2005 census figures was around 391,500. Using this latter figure as the denominator the prevalence of diabetes in the Maltese population in 2000 was 9.96%. The UK average prevalence in 2011 was reported as 4.45% while in Germany this is reported to be 7.7%.

Until September 2007 patients with vascular disease were cared for by general surgeons with a vascular interest who provided on call cover on a 1 in 3 basis. Their vascular work was in addition to their general surgery commitment. In August 2007 a vascular surgeon who had trained and become a Consultant in a UK vascular unit, was appointed to the service and as from September 2007 started to contribute to the vascular service. The vascular surgeon's clinical commitment was solely in vascular disease. The national vascular on call cover as from September 2007 was provided by the vascular surgeon on alternate weeks and by one of the three general surgeons with a vascular interest on the other week. This meant that as from September 2007 50% of the workload was taken by the vascular surgeon while the other 50% was shared between the three general surgeons with a vascular interest. In January 2014 another vascular surgeon was recruited to the service and all patients with vascular disease were treated by a vascular team. The three general surgeons with a vascular interest withdrew from the vascular on call rota and the vascular service. All diabetic foot related complications were treated by vascular specialists during this last period irrespective of whether the main pathology was ischaemia. Even cases where there was no significant peripheral arterial disease but where diabetic foot infection, usually in the context of peripheral neuropathy, was the main threat to the limb were cared for by vascular specialists.

The aim of this study was to assess the impact of the introduction of a specialist vascular service on lower limb major and minor amputation rates and open revascularisation procedures in a population with such a high prevalence of diabetes.

Materials and methods

This is a retrospective analysis of prospectively collected data over a period of 13 years between January 2002 and December 2014. Data was obtained from two main sources. The first source was the Annual Hospital Surgical Operation reports published by the Medical administrator's office for the main referral hospital for the years 2002-2014. The second source was the Vascular Database held by the vascular unit at the same hospital. The vascular unit was set up in late 2007 and complete data is available since the database was set up (2008-2014). The vascular database recorded all hospital activity performed by the vascular specialists.

The data collated from the Annual Hospital Surgical Operation reports included the total annual number of major lower limb amputations and the types of amputation (transfemoral, transtibial, other), the total annual number of minor amputations and the types of amputation (toe amputations or transmetatarsal and other foot amputations) and the total annual number of open revascularisation procedures (including aortofemoral, axillofemoral, common femoral endarterectomies, infrainguinal bypass procedures). The Annual Hospital Surgical Operation reports included procedures done by all surgeons working

in the hospital. The data is collected from the register kept in each operating theatre in the hospital which documents the case done and which is countersigned by the operating surgeon. The Annual Hospital Surgical Operation reports are based on this data which is anonymised and therefore information about mortality is not available. The data available relates to the number of each type of procedure performed. The data is inputted in real time including the time at which the patient enters and leaves theatre. The only possible inaccuracies in this data may relate to any errors in the type of procedure documented by the surgeon although the probability of errors in the type of procedure performed is low.

The data collated in the Vascular Surgical Database included all the procedures performed by the vascular specialists only. The data included the total annual number of major amputations and the type, the total annual number of minor amputations and the type as well as the total annual number of open revascularisation procedures performed by the vascular specialists. Data is also collated in this database on risk factors including diabetes, renal disease, smoking, hyperlipidaemia. cardiac disease and carotid status based on the recommended standards for reports dealing with lower extremity ischemia issued by the Society for Vascular Surgery.[12] Mortality data can be derived for the cohort of patients in this group but mortality data was not reported in this paper as this information was only available for data obtained through the vascular surgical database but not through the Annual Hospital Surgical Operation reports.

Data was analysed in two ways. Firstly the data was analysed by time period. Period 1 covered the six year period between 2002 and 2007 during which the vascular service in the hospital was provided by general surgeons with a vascular interest. Period 2 covered the six years between 2008-2013 during which half the workload was covered by the vascular specialist and the other half by the same general surgeons with a vascular interest. Period 3 covered between January to December 2014 when all patients with vascular disease were treated by a vascular team with minimal involvement of the general surgeons with a vascular interest. All the data collated in Period 1 was compared to the data in Period 2 irrespective of the type of consultant providing care. Data for period 2 (2008-2013) was also analysed according to the type of caring consultants providing care (vascular specialist or general surgeons with vascular interest).

All teams (whether vascular or general with a vascular interest) practised in the same institution and had equal access to all resources including endovascular interventions, access to interventional radiologists, multidisciplinary team meetings, imaging facilities, theatre facilities and patient bed availability. All conditions in both groups were identical (same institution, same facilities, same time period) with the only variable between the two groups being the type of consultant.

By comparing the data from the vascular database and the data from the Annual Hospital Surgical Operations reports it was possible to determine how many procedures were performed by the vascular specialists and how many by all other surgeons during the study period.

Independent t-test was used to compare means for the three study periods and Chi square test was used to analyse groups based on caring consultant (vascular surgeon or general surgeons with a vascular interest). SPSS version 22 statistical software package was used.

Results

Major amputations

Between January 2002 and December 2014 a total of 1366 major lower limb amputations were performed. Figure 1 shows the total number of major amputations performed each year during this time period. During Period 1 (2002-2007) 725 major amputations were performed giving an average of 120 major amputations/year. During Period 2 (2008-2013) the total number of major amputations was 577 giving an average of 96/year while in Period 3 (2014) 64 major amputations were performed. There was a significant reduction in major amputations between Period 1 and Period 2 ($p=0.008$). 218 less major amputations were performed during period 2 compared to period 1. There was an even more significant reduction between Period 1 and Period 3 ($p<0.001$).

The peak in major amputations performed was reached in 2003 when 133 were done. During the last year of the study (2014) 64 major amputations were performed, constituting a 51.8% drop in major amputations between 2003 and 2014.

***Figure 1**: Major amputations: number of total, transfemoral and transtitibial amputations performed between 2002-2013.*

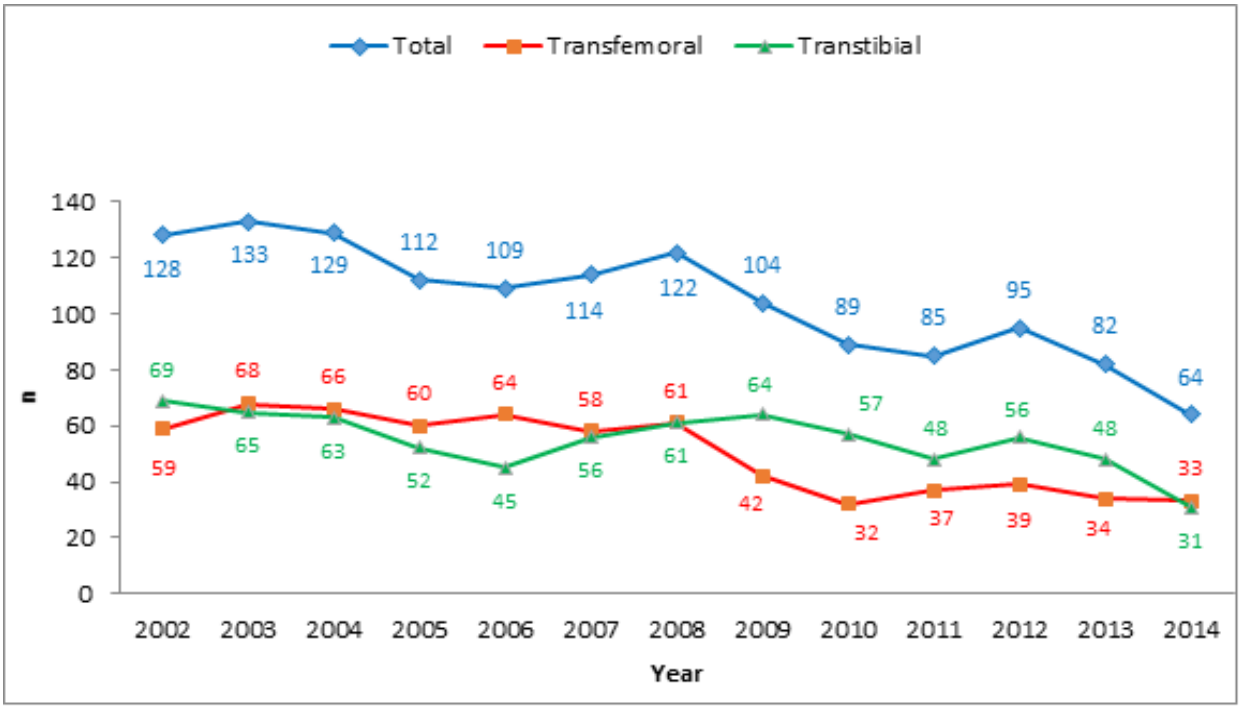
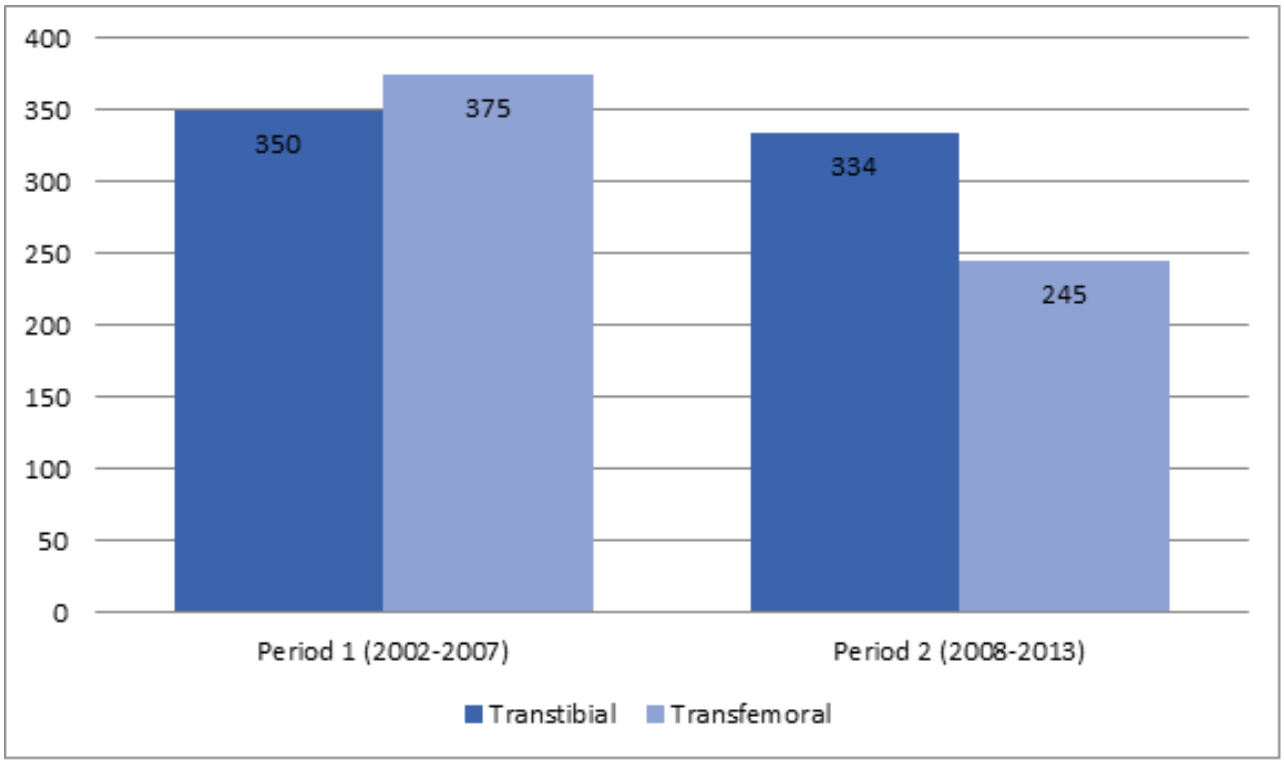


***Figure 2**: Major amputation levels during period 1 (2002-2007) and period 2 (2008-2013)*



The peak during period 1 reached in 2003 is equivalent to a rate of 33 major amputations per 100,000 population (based on 2005 census population figure). The trough reached in 2014 equates to 15.8 major amputations per 100,000 population (based on 2011 census population).

Figure 2 shows the types of major amputations performed during periods 1 and 2. During the whole period 653 transfemoral amputations and 713 transtibial amputations were performed. This equates to a transtibial to transfemoral ratio of 1.15 for the whole period. During period 1, 375 transfemoral amputations and 350 transtibial amputations were performed equating to a transtibial to transfermoral ratio of 0.93. During period 2, 245 transfemoral and 334 transtibial amputations were performed. This equates to a transtibial to transfemoral ratio of 1.36. The difference between the two periods in level of amputation was statistically significant (p<0.001).

Minor amputations

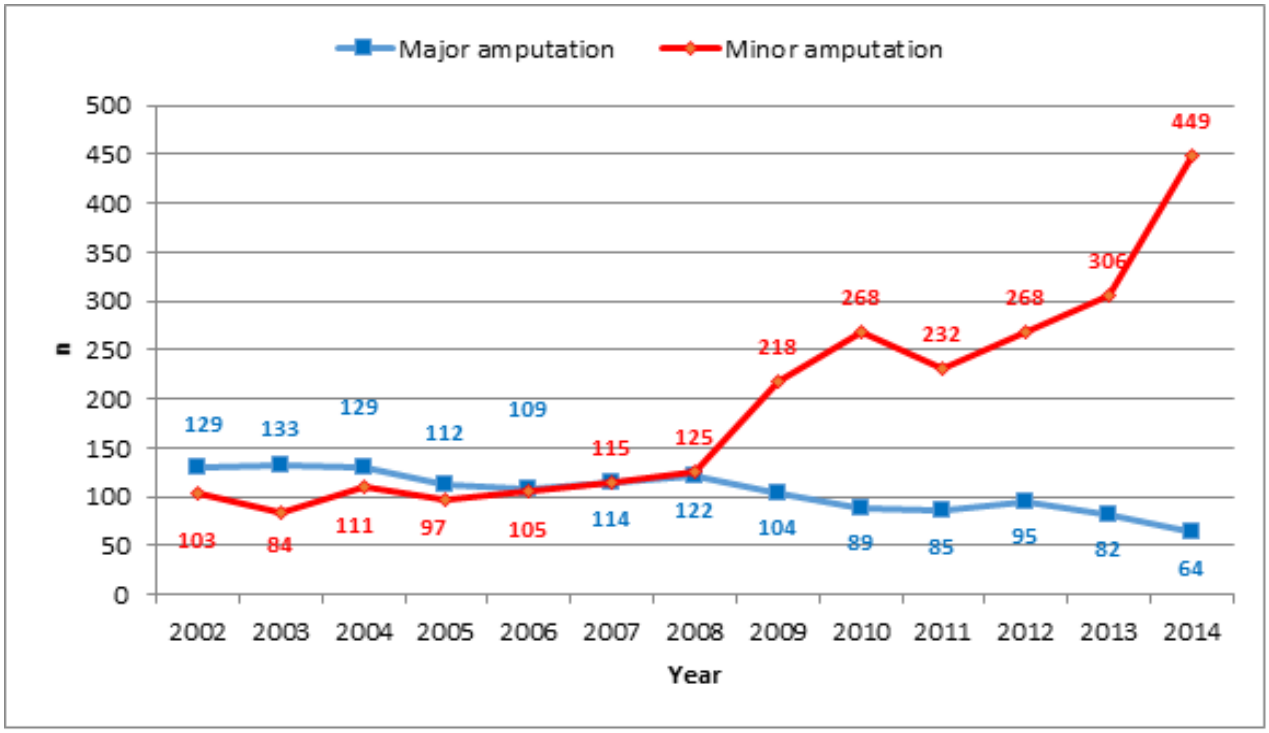
The total number of minor amputations during this period was 2521 with an average of 102/year during period 1 and 242/year in period 2 accounting for a 137% increase. In period 3, 449 minor amputations were performed constituting a 340% increase (p<0.001). The peak during period 1 was 115/year in 2007 while the peak in period 2 was 306/year in 2013 increasing to 449 in period 3.

The vast majority of foot amputations were toe amputations at the level of the proximal phalanx or metatarsal. Only a small proportion were transmetatarsal or higher foot amputations. During period 1 a total of 67 transmetatarsal or higher foot amputations were performed while in period 2 this increased to 142 (112% increase). The mean annual rate of transmetarsal amputations increased significantly from period 1 to period 2 (11.33 vs 23.5; *p=0.01*) and remained steady during 2014 (23/year)

The number of toe amputations in period 1 was 547 compared to 1316 in period 2 (140% increase). Again there was a significant increase in mean toe amputations performed annually between period 1 and period 2 (91 vs 219; *p<0.001*) and a further significant increase to period 3 (91 vs 449; p<0.001). The increase from period 2 to period 3 was also significant (*p=0.01*).

Figure 3 shows the inverse relationship between minor amputations (below ankle) and major amputations (above ankle) over the 13 years of the study.

***Figure 3**: Number of Major (above ankle) and minor (below ankle) amputations performed between 2002 and 2014*



Revascularisation procedures

712 open revascularisation procedures were performed in total. Of these 439 (61.6%) were performed during period 2. During period 1 a mean of 21.5 procedures were performed per year, during period 2 this increased to 73.2/year (240% increase; *p<0.001*) and increased further to 144/year in Period 3. Figure 4 shows the number of open revascularisation procedures during the study period.

Figure 5 shows the inverse relationship between revascularisation and major amputation rates.

Data analysed by type of caring surgeon Period 2 (2008-2013)

During period 2, 577 major amputations were performed of which 212 (36.7%) were performed by a vascular specialist while 365 (63.3%) were performed by the general surgeons with a vascular interest.

During period 2, 439 open revascularisation procedures were performed in total. Of these 359 (81.8%) were performed by the vascular surgeon compared to 80 (18.2%) by all 3 general surgeons with a vascular interest.

With regards to minor amputations a total of 1457 were performed during period 2 of which 1023 (70.2%) were performed by the vascular surgeon compared to 434 (29.8%) by the general surgeons with a vascular interest.

The total number of open revascularisation, minor and major amputations performed by the vascular surgeon in Period 2 were 1594 (64.5%) while for the general surgeons with a vascular interest this was 879(35.5%) during period 2.

Figure 6 shows the total number of major amputations and revascularisation procedures performed by caring consultant type. The ratio of major amputation to revascularisation for the general surgeons with a vascular interest was significantly higher than for the vascular surgeon (4.56 vs 0.59; *p<0.001*). The vascular surgeon performed 154 transtibial amputations and 58 transfemoral amputations during period 2 giving a transtibial to transfemoral ratio of 2.66. The general surgeons with vascular interest performed 180 transtibial and 187 transfemoral amputations giving a transtibial to transfemoral ratio of 0.96. (*p<0.001*)

Figure 4: *Open revascularisation procedures performed between 2002 and 2014 by General surgeons with a vascular interest and vascular specialists*

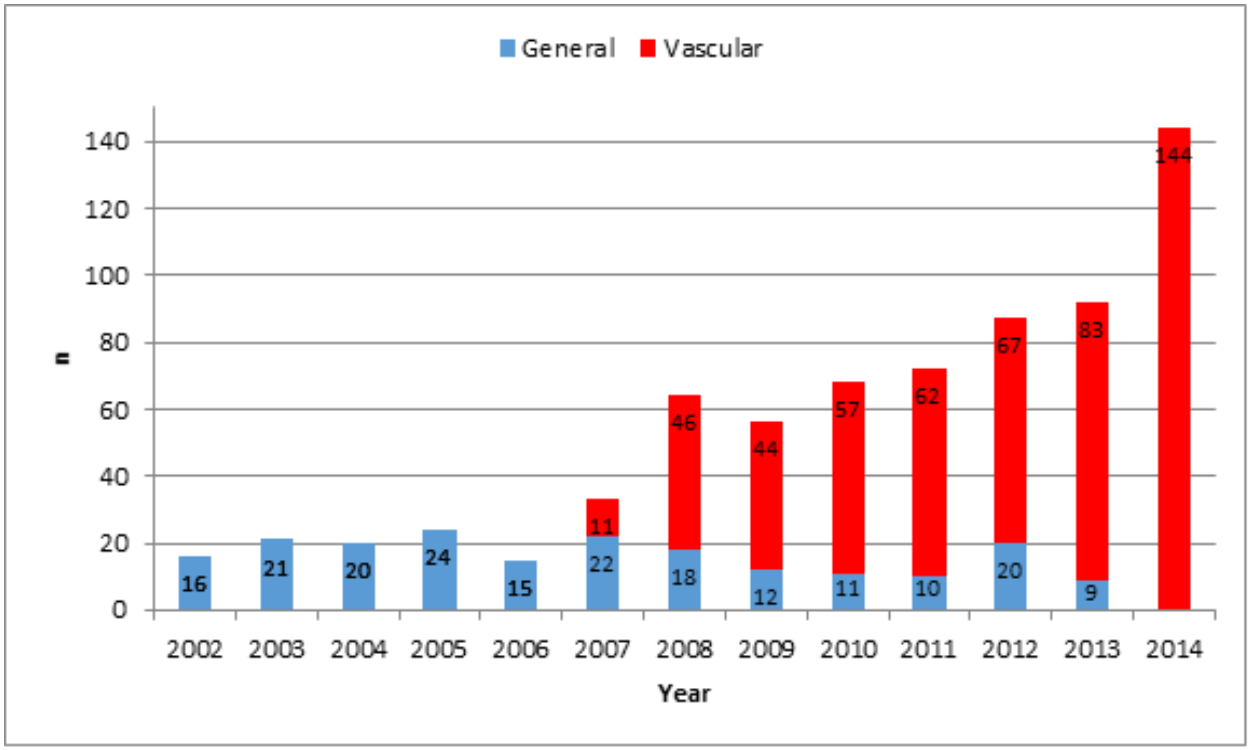


***Figure 5**: Relationship between major amputations and open revascularisation procedures between 2002 and 2013*

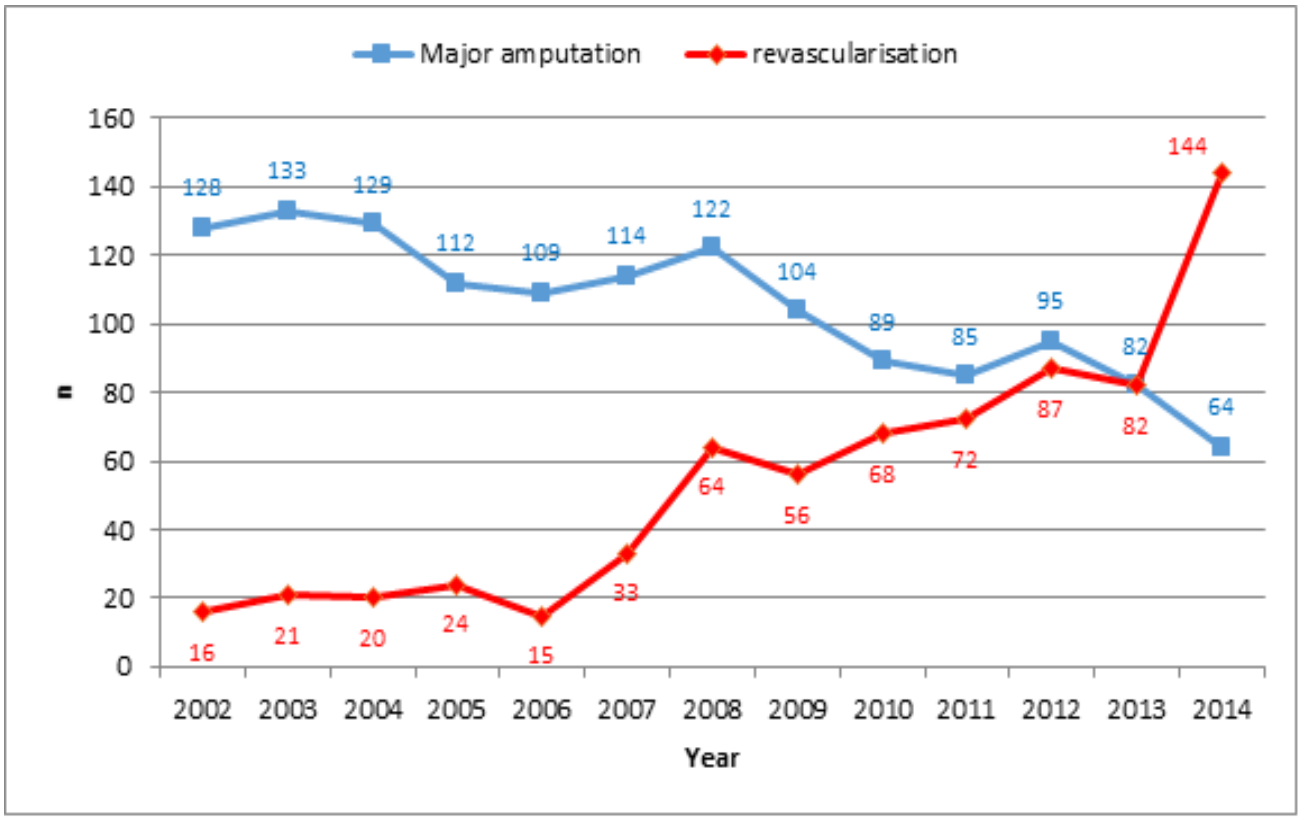
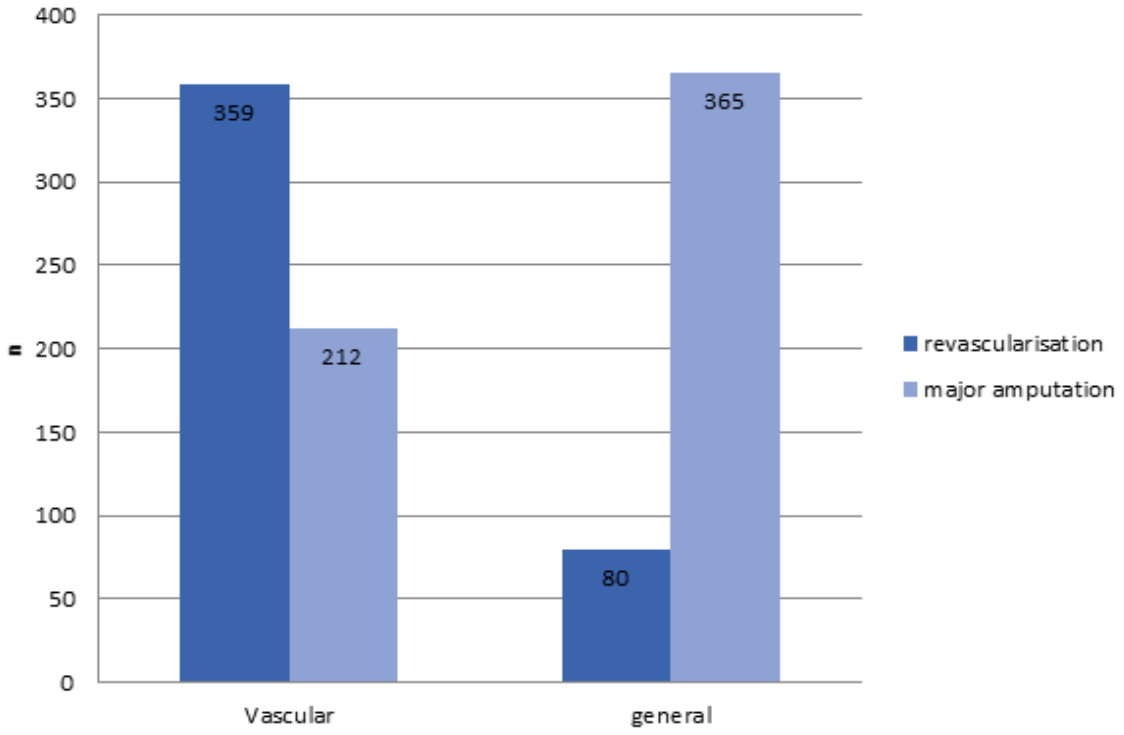


***Figure 6**: Open revascularisation and major amputations performed by vascular specialist and general surgeons with vascular interest during period 2 (2008-2013)*



Discussion

This study shows that the introduction of vascular specialists can have a very significant impact on major amputation rates and revascularisation rates. The data suggests that the addition of a vascular specialist to the existing consultant body led to a very marked increase in open revascularisation and minor amputation rates as well as a marked reduction in major amputations. The practice of the general surgeons with a vascular interest would necessarily include other surgical procedures limiting their time dedicated to vascular surgery.

Once the service was offered by vascular surgeons only there was a further significant increase in revascularisation and a significant reduction in major amputations. In this study a 51.8% reduction in major amputations occurred within 7 years of recruitment of vascular specialists. This is despite the fact that the size of the population increased significantly and the number of diabetics who are the main risk group for major amputation had also risen during the course of the study.

The level of major amputation shifted from a majority of transfemoral amputations during the period during which the general surgeons provided care, to a majority of transtibial amputations once vascular specialists started to contribute to the service. The total number of both transfemoral and transtibial amputations decreased but with a significantly bigger reduction in transfemoral amputations.

This study has also shown that the outcomes for patients cared for by vascular specialists differ from those of patients taken care of by general surgeons with a vascular interest. The revascularisation rate is significantly higher and the major amputation rate is significantly lower for those under the care of a vascular surgeon. In addition, for those requiring major amputation it is far likelier for patients to undergo a transtibial rather than a transfemoral amputation. This translates into significantly lower operative mortality rates and better rehabilitation rates although mortality data was not presented in this paper.

The differences observed between the outcomes of patients under the care of different types of consultant in this study is likely to be due to the type of caring consultant since there were no other obvious variables. The different teams worked in the same institution and cared for the same population during the same time period. The facilities available were identical for both groups. The selection of patients to the two groups was random as referrals of patients and acute admissions were on an alternate week arrangement between the vascular consultant and the 3 general surgeons with a vascular interest during Period 2. Most other studies have compared a study group with a historical group treated in a previous time period. The conditions for this study allowed a real time comparison of outcomes of patients cared for by different types of consultant within the same patient population during the same study period in the same institution.

The improvements noted in major amputation rates in Period 2 and again in Period 3 are likely to be due not only to the increase in revacularisation rates but also due to other developments during this period including an improvement in the endovascular revasularisation service, better organisation and access to clinics, development of multidisciplinary diabetic foot clinics, improvements in referral pathways and other changes brought about by recruitment of vascular specialists.

One of the limitations of the study is that no data was available about the total number of patients treated by both types of consultant. Having this data available would have given a clearer idea about the difference in approach (conservative vs interventional) between the two groups. Furthermore no overall mortality and morbidity figures were available for patients treated by both groups and hence outcomes for conservatively and actively treated patients cannot be surmised. This data would have been useful in comparing the composite endpoint of amputation free survival between the cohorts of patients treated by different consultant types. Another limiting factor is that no data is available about the risk factors of patients in the group treated by the general surgeons with vascular interest.

Conclusions

The cost of major amputations is significant and there is clear evidence that revascularisation is cost effective and results in cost savings to the health service.[13] The vast majority of patients requiring major amputations are often diabetics.

The projected increase in the prevalence of diabetes together with an aging population around the world suggests that the demand for vascular services is likely to increase. The evidence provided by this study, implies that training, recruiting and retaining vascular specialists particularly in geographical areas with a high prevalence of diabetes is a sound investment. The findings of this study indicate that recruitment of vascular specialists may be an effective way of increasing open revascularisation and reducing major amputation rates with the added benefits limb salvage provides to society.

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