

# Adequacy of clinical surveillance of diabetic patients requiring minor foot amputations

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## BACKGROUND

Minor amputations of foot complications related to diabetes have become increasingly more frequent in Malta. International recommendations suggest a standardised follow-up for patients with diabetes. We aim to compare the latter recommendations with a cohort of patients who underwent a minor amputation in the years 2014-2017.

## METHODS

Data was collected retrospectively from 101 patients with diabetes who were admitted to Mater Dei Hospital's Diabetic Foot Ward and required minor amputation. The audit parameters included patient demographics, specifics on the type of amputation performed, trending of relevant blood investigations prior to surgery and their follow-up history.

## RESULTS

A significant proportion of patients never had Hba1c (mean 4-year percentage of 34.4%), lipid (36.6%) or renal profile (23.3%) tested in the years leading to their amputations. Furthermore, the mean total Hba1c levels (78.7mmol/mol) showed that these patients with diabetes are mostly uncontrolled. A very large proportion of these patients were not seen at local health centres or diabetes outpatient clinics (65.4%). The majority were not seen by a podiatrist (61.4%), diabetes educators (84.2%) or ophthalmic specialists (51.5%) in the years preceding their amputation.

## CONCLUSION

Poor compliance with international guidelines for patients with diabetes is a contributing factor to the high rate of minor amputations. A co-ordinated effort to improve compliance with international standards relating to diabetes care is urgently required.

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## INTRODUCTION

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Foot pathology is the commonest indication for hospital admission in patients suffering with diabetes mellitus (DM). Malta, a European Union (EU) member state has one of the highest prevalence rates of DM.<sup>1</sup> The number of major limb amputations in Malta has decreased dramatically from a peak of 31/100,000/year in 2003 to 5.6/100,000/year in 2019. The number of minor foot amputations on the other hand remains significantly higher than in most other EU member states at between 76 - 86/100,000/year with an average of 414 minor amputations/year.<sup>2</sup>

There is no national diabetes register in Malta but the IDF Diabetes Atlas gives an estimate of 40,500.<sup>3</sup> A recent cross-sectional study highlighting the prevalence of type 2 diabetes mellitus in the Maltese Islands estimated a prevalence of ~44,400 which amounts to 10.31% of the population.<sup>1</sup> There is no national protocol or guideline for the follow-up of patients with DM. Primary health care is provided by local health centres which are nationally funded, and the private care service which is usually based on single general practitioners, podiatrists and other health care workers working separately and independently. There is no national foot screening programme and diabetes foot care is shared between public and private services.

Monitoring and surveillance of disease progression in patients with DM is guided by international recommendations such as the National Institute for Health and Care Excellence (NICE), the American Diabetes Association (ADA) and the International Diabetes Federation (IDF) which recommend:

- Hba1c testing every 3 months<sup>4</sup> and then every 6 months if levels are stable.<sup>5</sup>
- Patients should be followed-up regularly by a consultant endocrinologist if the desired

treatment goals are not reached. Patients with stable diabetes should still be followed up but longer intervals may be set.<sup>6</sup>

- Podiatry follow-up is also encouraged and patients are usually stratified by risk. This includes (1) low risk with annual foot assessment, (2) moderate risk every 3-6 months, (3) high risk with no immediate concern every 1-2 months and (4) high risk with immediate concern every 1-2 weeks.<sup>7</sup>
- Patients with Type 2 diabetes mellitus (T2DM) should be referred to diabetes educators at the time of diagnosis and the program should be available at the primary care level.<sup>4</sup>
- On diagnosis, GPs should immediately refer adults with T2DM to the local eye screening service. Annual appointments with an ophthalmologist familiar with the management of diabetic retinopathy should be organised. Patients who require more urgent assessment should be seen more regularly.<sup>6, 8</sup>

The aim of this study was to establish the level of compliance with international recommendations on monitoring and surveillance of patients with DM requiring minor foot amputations (amputations below the level of the ankle including amputation of digits at the phalangeal or metatarsal level), to assess the level of care of diabetes in the public health service and highlight any deficiencies in follow-up.

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## MATERIALS AND METHOD

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Patients with diabetes related foot complications requiring a minor amputation between January 2018 and April 2019 were selected for this project. These were identified from a hospital database obtained from the Clinical Performance Unit which focused mainly around the 'Diabetic Foot Ward' at

the main teaching hospital. Data was collected retrospectively using the local health care software system iSOFT, which allows accurate blood trending, records hospital admittance and monitors patient follow-up together with attendance. This was used to collect the following information:

- Demographics: gender, age
- Approximate date of diagnosis by noting first reported diabetes related follow-up and/or first known abnormal glucose levels. This confirmed that all patients were already known cases of diabetes.
- Blood investigation trending starting between 2014 to the date of admission Hba1c, glucose, lipid profiles and eGFRs levels and frequency of blood testing
- Patient visit history between 2014 to the date of admission including podiatry, diabetes education, ophthalmic, endocrine outpatients, community diabetes follow-up and follow-up post-amputation.
- Scheduling of follow-up up to 1 year after amputation with diabetes, vascular, podiatry, diabetes education and ophthalmic services.

Electronic case summaries were used to obtain information on hospital admittance/discharge, date and type of amputation. IBM SPSS Statistics (Version 26) was used for data analysis. Clearance was obtained from data protection office.

Mean totals and percentages were calculated to determine how many patients attended follow-up between 2014-2017. Chi-squared test was used to compare frequency of blood testing along the years.

The Kruskal-Wallis test was used to compare Hba1c levels with attendance to follow-up

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## RESULTS

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One hundred and one patients who were known cases of diabetes and underwent a minor amputation between January 2018 and April 2019 were included. Patient age ranged between 41 and 90 years. Male patients amounted to 65 (64.4%) while 36 (35.6%) were female.

A total of 119 amputations were performed, with some procedures involving amputation of more than one toe (table 1). Left foot amputations were noted to be more frequent than right foot amputations (53.5 vs 46.5%). The 1<sup>st</sup>, 2<sup>nd</sup> and 5<sup>th</sup> toes were the most frequently amputated while the 3<sup>rd</sup> and 4<sup>th</sup> toe were the least likely to require amputation. A significant proportion of patients had a 2<sup>nd</sup> toe amputation at the level of the proximal phalanx while patients with a 5<sup>th</sup> toe amputation were more likely to have surgery performed through the metatarsal.

Hba1c, renal profile and lipid profile testing levels since 2014 (table 2) indicate that a very significant proportion of patients never had HbA1c levels, lipid or renal profile checked. The proportion of patients without blood testing has decreased over the years. Hba1c levels in those patients who were tested were significantly above recommended levels in the vast majority of patients (table 3). LDL levels in the majority of patients were above the acceptable range i.e. 1.8 mmol/L (table 4). eGFR status of patients was classified according to the 2012 Kidney Disease: Improving Global Outcomes (KDIGO) guideline for chronic kidney disease evaluation <sup>[9]</sup> (table 5).

**Table 1** Frequency of amputated toes and the level of amputation

Toe	Frequency (n=19)	Proximal phalanx	Metatarsal
1st toe	38	19	19
2nd toe	31	20	11
3rd toe	13	8	5
4th toe	15	7	8
5th toe	22	3	19

**Table 2** Hba1c, lipid profile and renal profile testing frequency in the years preceding amputation

	Testing frequency	2014	2015	2016	2017	Mean tested	Mean %	P value
<b>Hba1c</b>	No test	43	34	35	27	34.8	34.4	0.130
	1 test	29	33	25	27	28.5	28.2	
	≥2 tests	29	34	41	47	37.8	37.4	
<b>Lipid profile</b>	No test	41	40	37	30	37	36.6	0.423
	1 test	31	28	26	27	28	27.7	
	≥2 tests	29	33	38	44	36	35.7	
<b>Renal profile</b>	No test	32	23	22	17	23.5	23.3	0.041
	1 test	19	19	17	10	16.3	16.1	
	≥2 tests	50	59	62	74	61.3	60.7	

**Table 3** Hba1c levels in the years preceding amputation

Years prior to amputation	Hba1c levels						Yearly mean Hba1c (mmol/mol)	4-year mean Hba1c (mmol/mol)
	<63.9	63.9–84.7	84.8–106.6	106.7–129	≥129	% >63.9		
4 years	19	24	13	6	3	45.5%	78.8	78.7
3 years	18	21	16	6	6	48.5%	82.3	
2 years	22	23	15	2	3	42.6%	77.5	
1 year	27	22	16	5	3	45.5%	77.7	
0 years	17	18	12	2	4	35.6%	77.7	

**Table 4** LDL levels in the years preceding amputation

LDL prior to amputation	Category	Frequency	% >1.8mmol/L	Mean LDL (mmol/L)	4-year mean LDL (mmol/L)
4 years	≤ 1.8	11	82.8	2.52	2.52
	> 1.8	53			
3 years	≤ 1.8	25	59.0	2.53	
	> 1.8	36			
2 years	≤ 1.8	10	85.2	2.63	
	> 1.8	52			
1 year	≤ 1.8	19	73.2	2.47	
	> 1.8	52			
0 years	≤ 1.8	17	76.6	2.46	
	> 1.8	36			

**Table 5** eGFR levels according to KDIGO categories in the years preceeding amputation

eGFR prior to amputation	eGFR levels						% <30	Yearly mean eGFR	4-year mean eGFR
	≥90	60-89	45-59	30-44	15-29	<15			
<b>4 years</b>	15	30	11	8	4	7	59.4%	64	57
<b>3 years</b>	10	26	14	13	7	6	65.3%	58	
<b>2 years</b>	11	29	14	9	8	7	66.3%	59	
<b>1 year</b>	11	26	15	13	9	10	72.3%	54	
<b>0 years</b>	12	18	12	11	6	11	57.4%	54	

Only 35 (34.7%) patients were seen at least once a year in the hospital or community. Hospital attendance (24 (23.8%)) was noted to be greater than community attendance (10 (9.7%)) overall. Those who were attending hospital only and community only had approximately 1-2 visits each year. Only 2 patients (2.0%), were seen in both community and hospital (table 6).

Between 2014-2017, prior to their amputation 66 (65.3%) patients were not booked for any diabetes care appointments either in the hospital or community, 12 (11.9%) failed to turn up and 2 (1.9%) had their appointment cancelled (table 6).

There was no significant difference noted ( $p=0.463$ ) when comparing Hba1cs in those followed up in hospital, community, both and those patients who were not being seen. (Table 7)

The majority of patients (62 (61.4%)) were not booked for podiatry visits in the 4 years preceding their amputation. Patients who were seen at least once a year (mean total of 39 (38.6%)) had ~2 visits/year between 2014-2017. Eighty-five patients (84.2%) had not been seen by the diabetes education team between 2014-2017. From those who attended, 15 (14.9%), had ~1-2 visits/year in the years preceding the amputation. A total of 48 patients (47.5%) had been seen at ophthalmology department at least once per year and 52 (51.5%) were not being followed-up by ophthalmology services (table 8).

Finally, patient follow-up scheduling up to 1 year post-operatively was also assessed as seen in table 9.

**Table 6** Attendance to hospital and community follow-up in the years preceding amputation

Attended follow-up	Hospital	Community	Both	Total seen	% total seen
2014	19	10	3	32	31.7
2015	28	9	0	37	36.6
2016	27	9	1	37	36.6
2017	22	11	2	35	34.8
4 year mean	24	10	2	35	34.7
No follow-up	Failed to attend	Visit cancelled	No documented follow-up	Total NOT seen	% total not seen
2014	13	0	56	69	68.3
2015	13	1	50	64	63.5
2016	9	4	51	64	63.5
2017	11	4	52	67	66.4
4 year mean	12	2	52	66	65.4

**Table 7** Hba1c levels vs hospital/community follow-up

	Frequency	Mean Hba1c (mmol/mol)	<i>P value</i>
Hospital only	39	74.9	0.463
Community only	11	76.1	
Attended both	11	62.7	
Never attended	39	66.1	

**Table 8** Attendance to podiatry, diabetes education and ophthalmic appointments in the years preceding amputation

	Years	Attended	% total seen	Failed-to-attend	Cancelled	No follow-up	Total without follow-up	% total not seen
<b>Podiatry</b>	2014	39	38.6	7	0	55	62	61.4
	2015	38	37.6	4	0	59	63	62.4
	2016	36	35.6	6	0	59	65	64.4
	2017	43	42.6	4	0	54	58	57.4
	4 year mean	39	38.6	5	0	56	62	<b>61.4</b>
<b>Diabetes education</b>	2014	10	9.9	1	0	90	91	90.1
	2015	15	14.9	4	0	82	86	85.1
	2016	11	10.9	3	0	87	90	89.1
	2017	25	24.8	2	0	74	76	75.2
	4 year mean	15	14.9	2	0	83	85	<b>84.2</b>
<b>Ophthalmic</b>	2014	45	44.6	4	0	52	56	55.4
	2015	51	50.5	5	1	44	50	49.5
	2016	54	53.5	2	0	45	47	46.5
	2017	45	44.6	8	2	46	56	55.4
	4 year mean	48	47.5	4	0	46	52	<b>51.5</b>

**Table 9** Follow-up 1 year postoperatively

Follow-up	Total scheduled follow-up	No scheduled follow-up	% total scheduled follow-up	% no scheduled follow-up
Diabetes	79	22	78.2	21.8
Vascular	97	4	96	4
Podiatry	96	5	95	5
Diabetes education	42	59	41.6	58.4
Ophthalmic	58	43	57.4	42.6

## DISCUSSION

This retrospective audit shows that local monitoring and surveillance of patients with diabetes who required minor amputation does not meet international recommendations.

A very significant proportion (34.4%) of patients undergoing minor amputations did not have Hba1c levels tested at all. On a positive note, improvement has been noted in HbA1c, renal and lipid profile testing between 2014 and 2017 (table 3). The majority of subjects having a minor amputation had uncontrolled T2DM with a mean total of Hba1c of 78.7mmol/mol i.e. 9.36%. This is usually associated with an increased risk of complications related to diabetes<sup>4</sup> (table 4). A mean eGFR of 57 shows that most patients are well below the normal level and this a strong predictor of macrovascular complications<sup>5,10</sup> (table 6). LDL levels were also noted to be well above the recommended level of 1.8mmol/l as set by the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS) guidelines for the management of diabetes<sup>11</sup> (mean total= 2.52) (table 5).

Since the selected cohort includes patients who have already developed complications it is not unexpected that their level of control falls short of

international recommendations. This retrospective analysis revealed that lack of control is mainly attributed to poor patient compliance and a failure of the system to book patients for appointments in the public health service offered. In addition, the very high rate of minor amputations in Malta suggests that poor compliance with international recommendations is more widespread.

In Malta there is no established guideline for diabetes referral, however an unofficial system exists where patients with well controlled diabetes are usually followed-up in the community by a GP while patients with uncontrolled T2DM are seen in hospital by an endocrinologist. From our cohort, a mean 4-year total of only 34.7% were seen in the hospital and/or community with hospital attendance (23.8%) being most predominant. A significant proportion of patients (65.3%) were not seen at all in the 4 years preceding the minor amputation. In most cases patients were simply not followed-up in a given year (51.5%) and only a handful failed-to-attend (11.9%) or had their appointment cancelled (1.9%). Patients followed-up in hospital are more likely to be the more complex cases and more likely to have higher Hba1c levels. The results however do not support this assumption and Hba1c levels in the community (76.1mmol/mol)

are only marginally higher than those seen in hospital (74.9mmol/mol) (table 7).

International guidelines recommend regular follow-up by podiatry, diabetes education teams and ophthalmology. This retrospective analysis showed that a very significant proportion of patients were not seen by podiatry (61.4%), diabetes education (84.2%) or ophthalmology (51.5%) in the 4 years preceding their amputation (table 8). In the year after their intervention most patients had better follow-up with their endocrinologist/GP, podiatry, diabetes education and ophthalmic. This shows that the measures put in place for follow-up of patients admitted for minor foot amputation are more effective (table 9).

One of the limitations of the study is that the results may not be representative of the general population due to the small cohort size. Also, selected patients are at a higher risk of developing complications and need more intensive follow-up. However, since 2014 an improvement in frequency of blood testing has been noted (table 3) while patient follow-up has remained roughly unchanged (table 7 and 8). Furthermore, since this is a retrospective audit, this analysis does not consider whether patients were being seen in private clinics and data is only limited to the public health service.

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## CONCLUSION

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This study highlights the poor compliance with international recommendations in those patients with diabetes who underwent a minor foot amputation. The data demonstrates that the very high levels of minor amputations in the country require a concerted effort to ensure that healthcare systems are put in place to improve compliance and quality of care to this vulnerable population. The fragmentation of health care provision and the lack of a national co-ordinated diabetes care service is likely to be in part responsible for the poor compliance. Further research is required to determine whether the implementation of more stringent and rigorous follow up in patients with diabetes will lead to a reduction in the number of minor amputations.

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