Prevalence and Predictors of Amputation in Diabetic Foot Complications in Western Region of Saudi Arabia: A Retrospective Study

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Abstract: **Diabetes foot complication is a life time risk to the diabetes patients that increases the morbidity and mortality.**

Objective: To assess the prevalence and predictors of amputations among patients with diabetic foot complications followed up at a diabetic foot center (DFC), in Jeddah, Saudi Arabia.

Methods: The current study was a retrospective analysis of diabetes patients registered at the DFC between Jan 2012 and Dec 2013, and were followed up for ≥ 3 month for diabetic foot ulcer. Data collected includes demographics, lifestyle, clinical factors, Wagner grade, accompanying clinical signs, associated factors (neuropathy, peripheral arterial disease [PAD], and foot trauma), management strategy, ulcer healing or amputation and mortality. Appropriate statistical tests were applied to identify the risk factors associated with amputation and binary logistic regression was used to analyze its predictors.

Results: In total 147 diabetic patients, 73.5% males, mean age (SD) 53.90(16.43) years, mean (SD) duration of diabetes 11.33 (7.53) years, 57.8% had right foot ulcer, 32.2% had high Wagner grade (grade 4-5). Prevalence of amputation was observed in 40.1% (95%CI=32.6- 48.2). Predictors of amputation were age, low income or educational level, long diabetes duration, irregular follow-up, hypertension or visual impairment, existence of two or more comorbidities. Ulcer-related predictors were higher Wagner grade, associated neurovascular abnormalities, and infections.

Conclusion: The current study suggests Wagner stage and association of co-morbidities as the major risk factors that predispose to amputation. Thus, enhance the need to recourse to specific therapeutic measures such as revascularization and surgical drainage.

Keywords: **Diabetic Foot, Complications, Ulcer, Gangrene, Amputation.**

1. INTRODUCTION

Diabetic foot complications (DFCs) are a serious threat to diabetic patients resulting in burdensome physical and psychological handicap and increased morbidity and mortality. Economically, diabetes foot complications cost almost 25% of the total diabetes-related healthcare expenditure.[1]

DFCs are responsible for almost 40% of major amputations, which are associated with high mortality (up to 70% for 5 years).[2,3]An epidemiological study in Saudi Arabia reported 16.7% of diabetes patients with foot disorders, leading to 1.8% of cases having foot ulcer, 1.5% having gangrene and 0.6% amputations.[4] These data are relatively consistent with those reported from other countries.[5] In 2012, Al-Zahrani estimated as 3970 the annual rate of diabetic foot-related amputations, among which 325 occurring in Jeddah. Author highlighted the necessity of national registries of diabetic foot and the urgent need for specific preventive and therapeutic measures.[6]

Diabetic foot complications develop more likely in patients with long duration of diabetes and are more frequent in those with poor glycemic control or who have micro- or macroangiopathy, such as peripheral vascular disease, retinopathy, ischemic heart disease and diabetic nephropathy.[5,7,8]

Diabetic foot ulcer is probably the major element of diabetic foot, which can be prevented by simple interventions that require multidisciplinary care in specialized services.[9,10]The comprehensive assessment of diabetic foot including meticulous skin, musculoskeletal, neurological and vascular examinations can allow detection of early disorders and assessment of underlying risk factors.[7] The most frequently used classification systems in ulcer assessment are the Wagner grade, the University of Texas classification and the Saint Elian Wound Score system. These classifications are based on the depth and penetration of the wound with presence or absence of ischemia, necrosis or infection.[11–13]

The management of diabetic foot aims at complete closure of the foot ulcer. However, the therapeutic option depends on the grade, vascularity and infectiveness of the wound and could range from specific ulcer dressing to more aggressive interventions such as minor or major amputations.[13–15]

2. AIM &RATIONALE

The aim of this study was to provide insights on the prevalence and outcomes of amputation in diabetes patients with foot complications at diabetic foot center. Insights on the other major diabetic foot ulcer outcomes include healing, recurrence, new ulcer and death will be published in another paper.

Providing such insight allows improving management of patients by defining categories of patients at high risk for recurrence, amputation or mortality, and who require higher level of care. Such data will also allow assessing the efficacy of the different therapeutic options offered in the participating center and highlighting areas of improvement in the daily practice.

3. METHODS

Study Design:

The current study was a retrospective analysis of patients with diabetic foot complications who were registered between January 2012 and December 2013 and followed up for ≥ 3 month at the diabetic foot center (DFC), King Fahd Hospital, Jaddah, Kingdom of Saudi Arabia. Both patients known as being diabetic at first registration and those diagnosed with diabetes during follow up in the DFC were included.

Data Collection:

A data collection form was designed including 4 parts: 1) demographic and socioeconomic data, such as gender, age at first registration, marital status, occupation, etc.; 2) lifestyle and clinical factors, such as smoking status, body mass index (BMI), diabetes duration (from diagnosis to first DFC registration), quality of diabetes follow up (regular/irregular), glycemic control (good/fair/poor), other medical history (hypertension, ischemic heart disease [IHD], nephropath), and treatment (diet, insulin, oral antidiabetic drugs [OAD]; 3) first assessment and management of diabetic foot, including location of the ulcer, date of onset, Wagner grade, accompanying signs (pulse, sensory loss, ankle reflex, infection), associated factors (diabetic neuropathy, peripheral arterial disease [PAD], and foot trauma), and first management strategy (relief of pressure, debridement of necrotic tissue, special dressing, biological active implants [BAI], revascularization, antibiotic therapy and surgical drainage; and 4) outcome data including patient and diabetic foot ulcer outcomes (healing/persisting unhealed/resolution by amputation or death), degree (minor/major) and level (toes/forefoot/below knee/above knee) of amputation and mortality.

Statistical Analysis:

Data was analyzed with the Statistical Package for Social Sciences version 21.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistics were carried out to calculate frequencies (N) and percentages (%) for categorical variable and means (standard deviations [SD]) for continuous variables. Appropriate statistics including chi-square test, Fisher's exact test and independent t-test were used to analyze demographic, socioeconomic, lifestyle, clinical and ulcer-related factors to identify the association of risk factors with foot amputation. Binary logistic regression was carried out to analyze significant risk factors as predictors for amputation. Statistical significance was set at p-value<0.05, and at 95% confidence interval (CI).

4. RESULTS

Demographic and socioeconomic Status of the population:

A total 147 diabetic patients were included in the analysis, of these 73.5% were males, mean (SD) age at study enrollment was 53.90 (16.43) years, 76.3% were married and having an average of 4-5 children. Of them, 48.3% and 24.5% were living in rural or Bedouin setting, respectively; 40.1% were of low economic class (<5,000 SAR per month income); and 40.8% were poorly educated.

Table 1: Demographic and socioeconomic status of the population

Parameter	Category	Frequency (n)	Percentage (%)
Mean Age (SD) years	--	53.90	16.43
Gender	Male	108	73.5
	Female	39	26.5
Nationality	Saudi	119	81.0
	Non-Saudi	28	19.0
Marital Status	Single	13	8.8
	Married	112	76.3
	Divorced	8	5.4
	Widowed	14	9.5
Mean number of children	--	4.55	3.11
Accommodation	Urban	36	24.5
	Rural	71	48.3
	Bedouin	36	24.5
Cohabitation	Alone	17	11.6
	With family	114	77.6
	With friends	2	1.4
Monthly income (SAR)	<5,000	59	40.1
	5,000 – 10,000	49	33.3
	10,000 – 15,000	33	22.4
	>15,000	6	4.1
Occupation	Employed	62	42.2
	Housewife	33	22.4
	Unemployed	23	15.6
	Retired	27	18.4
Educational level	Illiterate	30	20.4
	Primary	30	20.4
	Secondary	43	29.5
	University	39	26.5

Some values do not sum up to the total indicated in the column heading because of missing data.

Lifestyle and clinical characteristics:

Approximately half of the participants were active smokers (48.3%), majority (85.7%) practiced no regular exercise and more than 75% were overweight or obese. Type II diabetes (by reference to type I) was predominant, accounting for 79.6% of the participants. Diabetes follow up was irregular (77.6%) for majority of the participants and glycemic control was poor in one third (33.3%) of them. Treatment included 94.6% patients on diabetes diet, 77.6% on oral antidiabetics (OADs) and 26.5% on insulin, jointly or separately. The most frequent comorbidity was hypertension (49.0%); followed by dyslipidemia (22.4%), visual impairment (20.4%) and ischemic heart disease (IHD, 15.0%).

Assessment, management and outcomes of diabetic foot ulcer:

The mean±SD time from diabetes diagnosis to ulcer onset was 11.32±7.48 years and ranged between -2.08 and 29.83 years as 4 patients were diagnosed with diabetes after ulcer onset in the DFC. Foot ulcer was located in the right limb in 57.8% and bilateral in 4.1% cases; with high Wagner Grade 4-5) in 32.2% cases. First visit neurovascular assessment showed pulse reduction or absence in 23.8%, sensory loss in 38.8%, ankle reflex reduction or absence in 29.2%; and ulcer was infected in 78.2% cases. Other associated factors included neuropathy, PAD and foot trauma, which were present in 32.7%, 8.2% and 6.1%, respectively. Regarding treatment, majority of the patients benefited from pressure relief (95.9%), debridement of necrotic tissue (93.9%) and systemic antibiotics (95.9%); while 10.2% benefited from revascularization, 3.4% from bioactive implants and 42.2%underwent surgical drainage. Regarding outcomes, ulcer was healed in 64.6%, the prevalence of amputations was in 40.1% (95%CI=32.6, 48.2%; mean±SD time from ulcer onset=7.33±2.09 months) including 17.7% major and 22.4% minor amputations. Mortality rate was 3.4%.

Risk factors associated with amputation among patients with diabetic foot ulcer:

Patients who underwent amputation were older (p=0.001), had more children (p=0.003), lived higher percent in rural or Bedouin towns (p=0.007) and had low income (p=0.001) and low educational level (p<0.00001) when compared to those who did not underwent amputation.

Table 2: Demographic and socioeconomic factors associated with amputation among patients with diabetic foot ulcer

Factor	Category	No amputation (N=88)		Amputation (N=59)		p-value
		n/Mean	%/SD	n/Mean	%/SD	
Mean Age (SD), years		50.31	17.57	59.25	12.93	.001*
Number of children		3.90	2.86	5.58	3.24	.003*
Accommodation	Urban	29	33.0	7	12.7	.007*
	Rural	43	48.9	28	50.9	
	Bedouin	16	18.2	20	36.4	
Monthly income (SAR)	<5K	24	27.3	35	59.3	.001*
	5K – 10K	34	38.6	15	25.4	
	10K-15K	24	27.3	9	15.3	
	>15K	6	6.8	0	0.0	
Occupation	Employed	41	47.1	21	36.2	.045*
	Housewife	14	16.1	19	32.8	
	Unemployed	12	13.8	11	19.0	
	Retired	20	23.0	7	12.1	
Educational level	Illiterate	6	7.1	24	41.4	<.00001*
	Primary	14	16.7	16	27.6	
	Secondary	31	36.9	12	20.7	
	University	33	39.3	6	10.3	

* Statistically significant result (P<0.05); some values do not sum up to the total indicated in the column heading because of missing data;

Regarding lifestyle and clinical factors, patients who underwent amputation were less frequently active smokers (p=0.018); had longer diabetes duration (p=0.048) with more frequently irregular or not documented follow up (p=0.024); hypertension (p=0.0002), IHD (p=0.049), visual impairment (p=0.00035), nephropathy (p=0.021) and history of surgery (p=0.007) are the comorbidities associated with amputation; in addition to multiple pathology conditions (p=0.0001).They also were more frequently on insulin (p=0.010), antihypertensive drugs (p=0.002), anti-cholesterol (p=0.006) and platlet antiaggregant treatments (p=0.003) by comparison to their counterparts.

Table 3: Lifestyle and clinical factors associated with amputation among patients with diabetic foot ulcer

Factor	Category	No amputation (N=88)		Amputation (N=59)		p-value
		n/Mean	%/SD	n/Mean	%/SD	
BMI	Underweight	1	1.2	0	0.0	.238
	Normal	13	15.7	13	24.5	
	Overweight	27	32.5	17	32.1	
	Class I obesity	32	38.6	12	22.6	
	Class II obesity	8	9.6	8	15.1	
	Class III obesity	2	2.4	3	5.7	
Smoking status	Non-smoker	38	43.2	32	54.2	.018*
	Current smoker	49	55.7	22	37.3	
	Ex-smoker	1	1.1	5	8.5	
Regular exercise	Yes	1	1.1	1	1.7	.618
	No	74	85.1	52	89.7	
	Unknown	12	13.8	5	8.6	
Diabetes type	Type I	15	17.0	15	25.4	.217
	Type II	73	83.0	44	74.6	
Mean (SD) Diabetes duration, Years	--	10.33	6.85	12.83	8.27	.048*
Quality of diabetes follow-up	Regular	16	18.2	3	5.1	.024*F
	Irregular or not documented	72	81.8	56	94.9	
Glycemic control	Good	4	4.5	4	6.9	.315
	Fair	58	65.9	31	53.4	
	Poor	26	29.5	23	39.7	
Comorbidity	Hypertension	32	36.4	40	67.8	.0002*
	Hypercholesterolemia	16	18.2	17	28.8	.138
	Atherosclerosis	5	5.7	6	10.3	.346
	IHD	9	10.2	13	22.0	.049*
	Stroke	2	2.3	6	10.2	.060 F
	Visual impairment	9	10.2	21	35.6	.00035*
	Nephropathy	0	0.0	4	6.8	.021*
	Surgery	6	7.1	10	17.2	.007*
Number of comorbidities	None	44	52.4	11	19.3	.0001*
	One	21	25.0	16	28.1	
	2 or more	19	22.6	30	52.6	
Diabetes treatment	Diet	84	95.5	55	93.2	.714F
	Oral antidiabetic	73	83.0	41	70.7	.080
	Insulin	19	21.8	20	35.1	.010*
	Anti-cholesterol	13	14.8	19	32.8	.006*
	Platelet antiaggregant	8	9.1	16	27.1	.003*
	Antihypertensive	26	29.5	33	55.9	.002*

F:significance calculated using Fisher's exact test ; * statistically significant result (P<0.05) ; some values do not sum up to the total indicated in the column heading because of missing data.

Regarding ulcer-related factors, amputation was associated with higher Wagner grades (p<0.0001); more frequent neurovascular abnormalities including pulse reduction or absence (p<0.0001), sensory loss (p<0.0001), ankle reflex reduction (p<0.0001), neuropathy (p<0.0001) and PAD (p=0.016); and more frequent ulcer infection (p=0.041). Patients who underwent amputation benefited more frequently from specific therapeutical measures including special dressing (p<0.0001), bioactive implants (BAI) (p=0.005), revascularization (p<0.0001) and surgical drainage (p<0.0001).

Table 4: Ulcer-related factors associated with amputation among patients with diabetic foot ulcer

Factor	Category	No amputation (N=88)		Amputation (N=59)		p-value
		n/Mean	%/SD	n/Mean	%/SD	
Interval from diabetes diagnosis to ulcer onset (years)		10.32	6.80	12.81	8.23	.047*
Ulcer location	Right	53	60.2	32	54.2	.728
	Left	32	36.4	24	40.7	
	Bilateral	3	3.4	3	5.1	
Wagner Grade	Grade 0	3	3.4	0	0.0	<.0001*
	Grade 1	57	64.8	3	5.1	
	Grade 2	12	13.6	2	3.4	
	Grade 3	12	13.6	10	16.9	
	Grade 4	3	3.4	23	39.0	
	Grade 5	1	1.1	21	35.6	
Other clinical signs	Pulse absence	7	0.8	28	47.5	<.0001*
	Sensory loss	17	19.3	40	67.8	<.0001*
	Reduced ankle reflex	9	10.2	34	57.6	<.0001*
	Infection	66	75.0	49	83.1	.041*
	Neuropathy	16	18.2	32	54.2	<.0001*
	PAD	3	3.4	9	15.3	.016*
	Foot trauma	4	4.6	5	8.5	.395
	Other factors	7	8.0	5	8.5	1.000
Ulcer management	Pressure relief	84	95.5	57	96.6	1.000 F
	Debridement	82	93.2	56	98.2	.246 F
	Special dressing	29	33.0	40	67.8	<.0001*
	Bioactive implants	1	1.1	4	7.3	.005*
	Revascularization	2	2.3	13	23.6	<.0001*
	Antibiotics	83	94.3	58	89.3	.402
	Surgical drainage	22	25,6	40	75.5	<.0001*

PAD: Peripheral Arterial Disease; * statistically significant result (p<0.05)

Predictors for amputation:

Most significant demographic and socioeconomic predictors of amputation among diabetic patients with foot ulcer included having older age, living in rural or Bedouin town, and having low income or low educational level. Lifestyle and clinical predictors included long diabetes duration; irregular follow up; comorbid hypertension or visual impairment; existence of 2 or more comorbidities; and being treated with insulin, anticholesterol, platelet antiaggregant or antihypertensive drugs. Ulcer-related predictors included higher Wagner grade (grade 4-5>2-3>0-1); associated neurovascular abnormalities including pulse absence or reduction, sensory loss, ankle reflex reduction, neuropathy, PAD and infection; and the necessity to recourse to specific therapeutical measures including special dressing, revascularization and surgical drainage. Results of all explored predictors are presented as odds ratio (OR [95%CI]) with significance level for each predictor category in Table 5.

Table 5: Predictors of amputation among patients with diabetic foot ulcer (univariate binary logistic regression)

Predictors	Category	Odd's Ratio	95% CI		p-value
			Min.	Max.	
Demographic and socioeconomic factors					
Age at first registration		1.04	1.01	1.06	.002*
Number of children		1.20	1.06	1.37	.004*
Accommodation	Urban	Ref	-	-	.009*
	Rural	2.70	1.04	7.00	.041*
	Bedouin	5.18	1.80	14.88	.002*
Income	<5K	Ref	-	-	.006*
	5K-10K	0.30	0.14	0.67	.003*
	10K-15K	0.26	0.10	0.65	.004*
	>15K	I	I	I	I
Occupation	Employed	Ref	-	-	.051
	Housewife	2.65	1.11	6.31	.028*
	Unemployed	1.79	0.68	4.73	.241
	Retired	0.68	0.25	1.87	.459
Educational level	Illiterate	Ref	-	-	<.0001*
	Primary	0.29	0.09	0.90	.032*
	Secondary	0.10	0.03	0.30	<.0001*
	University	0.05	0.01	0.16	<.0001*
Lifestyle and clinical factors					
Smoking status	Non-smoker	Ref	-	-	.035*
	Current smoker	0.53	0.27	1.06	.073
	Ex-smoker	5.94	0.66	53.48	.112
Diabetes duration	(years)	1.05	1.00	1.09	.051
Quality of diabetes follow-up	Regular	Ref	-	-	.030*
	Irregular or undocumented	4.15	1.15	14.94	.008*
Comorbidity[‡]	Hypertension	3.68	1.83	7.40	.0002*
	IHD	2.48	0.98	6.25	.054
	Visual impairment	4.85	2.03	11.60	.0004*
	Nephropathy	I	I	I	I
	Surgery	2.71	0.93	7.93	.069
Number of comorbidities	None	Ref	-	-	.0002*
	One	3.05	1.21	7.70	.018*
	2 or more	6.32	2.63	15.16	<.0001*
Insulin	Yes	Ref	-	-	.020*
	No	0.45	0.21	0.97	.041*
Anticholestreol	Yes	Ref	-	-	.031*
	No	0.34	0.15	0.76	.008*
Platlet antiaggregant	Yes	Ref	-	-	.016*
	No	0.26	0.10	0.65	.004*

Antihypertensive	Yes	*Ref*	-	-	.005*
	No	0.32	0.16	0.64	.001*
Ulcer-related factor					
Interval Dx to ulcer onset	(years)	1.05	1.00	1.10	0.050
Wagner grade	Grade 0-1	*Ref*	-	-	<.0001*
	Grade 2-3	10.00	2.59	38.61	.001*
	Grade 4-5	220.00	46.85	1033.01	<.0001*
Other clinical signs	Pulse absence	10.67	4.22	26.99	<.0001*
	Sensory loss	9.83	4.52	21.35	<.0001*
	Reduced ankle reflex	13.85	5.75	33.36	<.0001*
	Infection	8.91	1.21	70.83	.039*
	Neuropathy	5.33	2.53	11.24	<.0001*
	PAD	5.10	1.32	19.72	.018*
Ulcer management	Special dressing	4.79	2.33	9.84	<.0001*
	Bioactive implants	7.40	0.80	68.15	.077
	Revascularization	14.33	3.09	66.59	.001*
	Surgical drainage	10.58	4.64	24.13	<.0001*

OR: Odds-ratio; 95%CI confidence interval; *ref*: reference category; ***** statistically significant result (p<0.05); I: invalid result; [‡] presence versus absence of the given comorbidity; IHD: ischemic heart disease; Dx: diabetes diagnosis;

5. DISCUSSION

Diabetes foot ulcer is the most frequent complication which poses morbidity and mortality in the affected individual. Clinical practice studies reported that 6–43% of patients with diabetes and a foot ulcer in due course progress to amputation. [8] The current study was a retrospective analysis of the prevalence and associated predictors for amputation in diabetes foot ulcer.

The analysis was extensive in studying all the possible parameters that are most likely to be associated with the foot ulcer and predispose to amputation. Many studies have reported that the risk factors that are associated with foot ulcers are also predisposing factors for amputation, because foot ulcers are primary leading cause for foot amputation. [16-18] Previous studies have shown that about 85% of all diabetes-related lower-extremity amputations are preceded by foot ulcers. [13]

Since diabetes is a complex condition and associated with many inherent and noninherent characters the current study highlights the significant association of age, female patients who are housewife, people living in Bedouin or rural town, and low income and educational levels with amputations (p<0.05). A previous health-related quality of life (HRQoL) study have reported that age, males, patients in low education level and living alone were significantly high in patients with foot ulcers and have low quality of life that may result in amputation. [19]

Long duration of disease with irregular follow-up and association of more than two comorbidites (such as hypertension, visual impairment) were observed to be significant indicators of amputations. Similarly, previous studies have shown the variables that significantly predicated ulcer healing and amputations depend on the wound age (duration in days) and size, infections, patient age, and Wagner grade and stage. [11] In addition patients who were on diabetes management with insulin are in high proportions in amputation group compared to their patient counterparts with no amputation; and insulin was shown to be a predictor of amputation among patients with diabetic foot ulcer. On the other hand, amputation was not correlated with diabetes type (type 1 versus type 2); which suggest that the significance of insulin treatment as a predictor for amputation may be related to the fact that insulin is generally initiated in advanced diabetes; which are more prone to severe outcomes [20]. Similarly, significance of other treatments including anti-cholesterol (OR: 0.34), platelet anti-aggregation (OR: 0.26) and antihypertensive (OR: 0.32) as predictors for amputation is most probably indicative of the related patient's comorbidity, rather than an adverse effect of the treatment.

The study also witnessed the strong association of clinical indications of foot ulcer onset and in patients who were at Wagner grade 2-3 and 4-5 ($p<0.05$), this alerts both the patient and the health care provider (clinicians or general physicians) to continuously follow up on the clinical observations at regular time interval. Many previous studied have reported the significant association of Wagner grades and ulcer stage on the patient outcomes such as amputation and mortality. [11] These results suggest to plan appropriate treatment strategy for diabetes foot ulcer based on the grade and stage of the condition to avoid severe consequences of the condition such amputation or death.

Diabetes foot ulcer management with bioactive implants, revascularization, special dressing and surgical drainage which are generally used in severe cases have shown the high rate of amputations ($p<0.05$). Prevention of ulcer is crucial to avoid amputations. Studies have shown that regular foot care examination (debridement), foot hygiene, therapeutic footwear with pressure-relieving insoles is essential to prevent and reduce the burden or complications of foot ulcers in diabetes [14, 21]. To best of our knowledge this is the first study to attempt to analyze various factors associated in diabetes foot ulcer leading to amputation in Saudi Arabian population.

6. LIMITATIONS

Several variables could not be collected as they were not available in the files. This limited further analysis such as Kaplan-Meier survival analysis, which could not be carried out because of missing time from ulcer to amputation data. A prospective study is warranted to ensure proper data collection of time variables and to draw out time predictive models of diabetic foot ulcer outcomes.

7. CONCLUSION

The current study reiterates the importance of the study of risk factors associated with foot ulcers that predisposed to amputations. However, as many studies have reported rather than ulcer-related outcomes which can underestimate the true morbidity and mortality, future diabetes studies are recommended to emphasize along with ulcer-related outcomes, patient-related outcome measures should also be given high importance.

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