Quality of life of diabetic patients with medical or surgical treatment

S. Weiner¹ and E. A. M. Neugehauer²

¹Surgical Department. Hospital Krankenhaus Sachsenhausen. Frankfurt. ²Institute for Research in Operative Medicine (IFOM). Faculty of Health-School of Medicine Witten/Herdecke University.

Abstract

Introduction: In general, most of the studies agree in that the quality of life (QoL) of patients with diabetes is worse than that of the general population. Furthermore, these same studies have also described very positive effects on quality of life after bariatric surgery. The aim of this study was to analyze whether the impact on quality of life of diabetic patients after being submitted to bariatric surgery is the one supposed to be.

Methods: We prospectively analyzed our data on 524 diabetic patients submitted to bariatric surgery between 2001 and 2005. All the patients filled up three QoL questionnaires before the surgery and at 1, 3, 6, and 12 months after the surgery. The answers were gathered from an annual database. All patients were submitted to adjustable gastric band surgery, Y-Roux gastric bypass, or BPD-Scopinaro.

Results: We obtained complete data on 89 patients that were included into the study. One year after the surgery, the QoL had significantly improved independent of disease remission and weight loss. Diabetes got improved in all the cases. The improvement on the quality of life was higher in the patients with total remission of the disease than in those only improving their health status, although it was lower than that of those patients without diabetes before the surgery.

Conclusions: After a literature review and with our own prospective data, we may conclude that the benefits obtained by diabetic patients from bariatric surgery are mainly due to improvement of their diabetes, irrespective of their initial BMI and the BMI decrease after the intervention. Further studies are needed to investigate the results of the QoL test in diabetics with low BMI after bariatric surgery and in the long run.

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Key words: Quality of life. Diabetes. Bariatric surgery. Metabolic surgery.

CALIDAD DE VIDA DE PACIENTES DIABÉTICOS; TRATAMIENTO MÉDICO VS CIRUGÍA

Resumen

Introducción: En general, la mayoría de los estudios coinciden en que la calidad de vida de las personas con diabetes es peor que la calidad de vida de la población general (QoL). Además, estos mismos estudios también han descrito efectos muy positivos sobre la calidad de vida tras cirugía bariátrica. El objetivo de este estudio fue analizar si el impacto sobre la calidad de vida de los pacientes diabéticos después de ser sometidos a cirugía bariátrica según el test (QoL) es el que se supone debería ser.

Métodos: Analizamos nuestra colección de datos prospectivos de 524 pacientes diabéticos que se sometieron a cirugía bariátrica entre 2001 y 2005. Todos los pacientes realizaron 3 cuestionarios de calidad de vida antes de la cirugía y después de 1, 3, 6 y 12 meses. Las respuestas se recogieron en una base de datos anual. Todos los pacientes se sometieron a una intervención de banda gástrica ajustable, Bypass Gástrico en-Y-Roux o BPD-Scopinaro.

Resultados: En total se obtuvieron los datos completos de 89 pacientes que fueron incluidos en el estudio. 1 año después de la cirugía, la calidad de vida mejoró de manera significativa e independientemente de la remisión de la enfermedad y de la pérdida de peso. La diabetes mejoró en todos los casos. La mejora en la calidad de vida fue superior en los pacientes con remisión de la enfermedad que en los que únicamente mejoraron su estado, pero inferior que en los pacientes que no tenían diabetes antes de la operación.

Conclusiones: Tras el análisis de la literatura y de nuestros propios datos prospectivos, podemos concluir que los beneficios que obtienen los pacientes diabéticos tras la cirugía bariátrica son debidos principalmente a la mejora de su diabetes, independientemente del IMC inicial y de la disminución del IMC tras la intervención. Se necesitan más estudios para investigar los resultados del test QoL en diabéticos con bajo índice de masa corporal tras la cirugía bariátrica y a largo plazo.

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Background

Unlike the clinical outcome (mortality, morbidity) typically measured in clinical trials, Health related Quality of Life (HRQOL) reflects the impact of medical procedures from the perspective of the patient, and thus provides a more holistic picture of procedures impact and recovery. Perception of patients HRQOL and its influencing factors will assist in developing strategies to improve HRQOL for diabetic patients with medical or surgical treatments.\textsuperscript{1,2}

As bariatric surgery is no longer only considered as a surgery only for the obese patient,\textsuperscript{3} but a metabolic procedure,\textsuperscript{4,5} quality of life became most important and measurements should be shifted to metabolic issues, too. The comparison of medically treated patients with surgical procedures on diabetic patients is of special interest related to changes in HRQOL.

Health related quality of life in diabetic patients

More than 180 million people worldwide have diabetes mellitus, and the number of diabetes patients is estimated to double by 2030.\textsuperscript{6} The increasing trend of diabetes has been reported for both, type 1 diabetes (T1D)\textsuperscript{7,8} and type 2 diabetes (T2D) populations.\textsuperscript{9,10}

Diabetes has detrimental effects on health outcomes including quality of life (QoL).\textsuperscript{11} Studies have shown significant negative associations between the disease state, health related quality of life (HRQOL) and its prognosis.\textsuperscript{12,13}

Further understanding of the determinants of HRQOL among individuals with diabetes could potentially help to tailor and to target interventional strategies for the benefit of this population group.

Medical and lifestyle determinants of HRQL and life satisfaction in adults with type 2 diabetes have been investigated in many studies\textsuperscript{14-18} and showed a multidimensional construct. Many factors with high impact on QOL were shown to be significantly associated with life satisfaction and HRQL in adults with T2D and T1D as well as in Adolescents\textsuperscript{19-21} and will be more differentiated in this article.

Measurement of Health Related Quality of Life (HRQL)

The two broad approaches to health-related quality of life measurement have emerged-generic and disease specific.

The generic approach involves the use of measures applicable across health and illness groups. The most widely used generic measure of quality of life in studies of people with diabetes is the Medical Outcomes Study (MOS) Short-Form General Health Survey\textsuperscript{22,23} in its several forms (SF-36, SF-20, SF-12).

The Rand Quality of Well-Being Self-Administered (QWB-SA) survey\textsuperscript{24} is similar to the SF-36 in its aim to comprehensively assess health-related well-being or quality of life. It contains scales designed to measure acute and chronic emotional and physical symptoms, mobility, and physical activity. Other instruments used at least occasionally to assess general health status in people with diabetes include the Sickness Impact Profile\textsuperscript{25} and the Nottingham Health Profile.\textsuperscript{26}

Generic measures like the SF-36 are most useful for comparing quality of life in people with different diseases and the quality of life in people who have no diseases with the quality of life in people who have a disease.

Such measures can be used to assess cost-effectiveness and cost benefits across various interventions and illnesses.

Many generic measures of emotional status have been employed in studies which include people with diabetes. These include the Well-Being Questionnaire,\textsuperscript{27} the Proile of Mood States,\textsuperscript{28} the Symptom Checklist (SCL-90R),\textsuperscript{29} the Mini-Mental Status Exam,\textsuperscript{30} the Kellner Symptom Questionnaire,\textsuperscript{31} and the Affect Balance Scale.\textsuperscript{32} Depression in people with diabetes has been studied using the following scales: the Beck Depression Inventory,\textsuperscript{33} the Zung Self-Rating Depression Scale,\textsuperscript{34} and the Center for Epidemiological Studies Depression Scale.\textsuperscript{35} Anxiety in people with diabetes has been studied using the following scales: the Beck Anxiety Inventory,\textsuperscript{36} and the Zung Self-Rating Anxiety Scale.\textsuperscript{37} Both depression and anxiety in people with diabetes have been studied using the Hospital Anxiety and Depression Scale.\textsuperscript{38}

The most widely used diabetes-specific quality of life measure is the Diabetes Quality of Life (DQOL) measure,\textsuperscript{39} developed for use in the Diabetes Control and Complications Trial (DCCT). The DQOL was designed to measure diabetes-specific quality of life. It contains scales to assess five separate areas: satisfaction with treatment; impact of treatment; worry about the future effects of diabetes; worry about social and vocational issues; and overall well-being. The last scale was derived from national surveys of quality of well-being and can be used to compare people with diabetes and a wide variety of other populations. The Satisfaction and Impact scales seem to be broad gauges of diabetes-related quality of life, whereas the Worry scales address concerns more specific to patient perceptions of diabetes-related emotional distress. Since the DQOL was introduced, a number of other comprehensive diabetes-specific quality of life measures have been developed. The Diabetes-39 instrument\textsuperscript{40} was developed for use with people who have either Type 1 or Type 2 diabetes \textit{whether} managed with insulin, oral agents or diet alone.

The Problem Areas in Diabetes (PAID) survey\textsuperscript{41} is a relatively new measure of psychosocial adjustment specific to diabetes. The PAID contains items measuring burden of illness, satisfaction with treat-
Quality of life and diabetes points to consider

Conceptualizing & measuring

Differences and associations

Complications

Type of diabetes

Glycemic control

Treatment regimen

Duration of diabetes

Demographic variables

Gender

Psychosocial predictors

1. People with diabetes

2. People without diabetes

Other chronic diseases

Diabetes per se

Improving quality of life

Quality of life and impact factors in conservative treatment of diabetes

Rubin et al described in 1999 in a systematic literature review the main impacts on QOL in diabetics patients (fig. 1). The main concerns will be displayed in the following.

Type of diabetes

Despite aetiological differences between T1D and T2D, differences in levels of HRQL and QoL as well as their determinants between the two diabetes types have not been thoroughly investigated in adults with diabetes. Jacobson and colleagues compared HRQL scores between 240 adults with T1D or T2D, and identified higher HRQL in T2D after adjusting for demographic factors (i.e., age, marital status and education), diabetes complications, and diabetes duration.

They used the SF-36 and the DQOL to assess quality of life and found that Type 2 patients not taking insulin reported higher quality of life that type 2 patients taking insulin. Type 2 patients on insulin still experienced better HRQOL that Type 1 patients.
Another study compared levels of three HRQL measures in adults (T1D, N = 236; T2D, N = 889) and found no differences in EQ-5D and QoL-DN scores between the two samples, but a higher global health profile (SF-36) score in the T2D group. Interestingly, in two studies on children and adolescents with diabetes, HRQL was lower among T2D individuals compared to those with T1D.

That age seems to be a strong variable in the outcomes of HRQL was also shown in the Alberta Longitudinal Exercise and Diabetes Research Advancement (ALEXANDRA) study in 2011. With the exception of age, the determinants of HRQL appear to be similar between T1D and T2D adults, suggesting that both diabetes groups may benefit from achieving generic approaches in targeting optimal control of glycemic level and comorbidities as well as promoting healthy lifestyle.

In fact, some researchers have found few meaningful differences between those with each type of diabetes in functional status or well-being.

Based on the limited available data, it is probably fair to say that while quality of life or some of its components may differ as a function of diabetes type, these differences are probably the result of other factors, such as treatment regimen or age, which are associated with diabetes type.

Treatment regimen

Results of research on the association between treatment regimen and quality of life in people with diabetes are mixed, with some indication that increasing treatment intensity in patients with Type 2 diabetes from diet and exercise alone, to oral medications, to insulin, is associated with worsening quality of life.

Presence of diabetes-related complications

The research addressing this question is consistent in finding that the presence of complications, particularly the presence of two or more complications, is associated with worsened quality of life both in studies with generic or diabetes-specific measures.

Main complications identified in these studies were presence of neuropathy, cardiovascular disease, nephropathy, gastroparesis, erectile dysfunction, diabetic retinopathy, and comorbidities as well as promoting healthy lifestyle.

Studies employing generic measures such as the SF-36, SF-20 often reported null findings. Only one study which used the SF-36 to assess quality of life found significant associations between HbA1c and some SF-36 scales in some sub-populations: Klein et al found that SF-36 general health and overall self-rated health scores were associated with HbA1c levels for younger onset subjects only (i.e. diagnosed before 30 years and taking insulin). Wikblad and colleagues reported that scores on the Swedish Quality of Life Scale (SWEDQUAL) were lowest for those with the highest HbA1c levels (8.1%), highest for those with HbA1c levels 7.1 ± 8.0%, and intermediate for those with the lowest HbA1c levels (7.0%).

This data suggests that there may be a curvilinear relationship between HbA1c level and health-related quality of life, perhaps as a result of decrements in quality of life associated with more complex treatment regimens or increased incidence of hypoglycemia.

Studies using disease-specific questionnaires support this suggestion, whereas studies using generic instruments (esp. SF-36) cannot show any relationship. This issue might be due to the fact that generic questionnaires may not adequately address the important issues of the diabetic patients - the effect could be shown by Tief et al in 1998.

A few studies have found no significant relationship between HbA1c levels and diabetes-specific measures of quality of life, but the HbA1c levels of the participants in these studies were quite low, averaging about 7.0%, so the restricted range of glycemia may have contributed to the null finding.

Some studies have found significant associations between quality of life and measures of glycemia other than HbA1c. Lower fructosamine levels were associated with higher DQOL treatment satisfaction scores and lower fasting plasma glucose levels were associated with lower levels of fatigue as measured by the Profile of Mood States.

Overall, the majority of studies suggest that better glycemic control is associated with better quality of life.

This association is stronger for measures of diabetes-specific quality of life and generic measures of emotional distress than for generic measures of quality of life.

Gender

A number of researchers have reported that quality of life is better among diabetic men than among diabetic women. This is consistent with reported gender differences in health-related quality of life in the general population. Rubin et al, published in 1998 that men were more satisfied with their diabetes treatment regimen, and missed less work and fewer leisure activities as a result of their diabetes, than women did. Peyrot et al found that treatment satisfac-
Differences in people with and without diabetes

In general, most studies report that quality of life among people with diabetes is worse than quality of life in the general population.

Impact of bariatric surgery on diabetes

Weight gain and obesity are driving the global epidemic of type-2 diabetes through metabolic and inflammatory pathways. Insulin resistance and impaired pancreatic beta-cell function, are the two important factors that are directly responsible for the development of this disease in susceptible populations. Lifestyle methods and modest weight loss are powerful in preventing and managing type-2 diabetes, but sustaining substantial weight loss is problematic. Bariatric surgery provides exceptional sustained weight loss and remission of type-2 diabetes in 50-85% of subjects, especially if treated early before irreparable beta-cell damage has occurred. In addition, there is substantial evidence that bariatric surgery provides additional comorbidity and quality-of-life improvements and reduces mortality in patients with type-2 diabetes. An association between the extent of weight loss and remission of type-2 diabetes has been shown.112 Diversionary bariatric procedures such as gastric bypass and biliopancreatic diversion induce a rapid non-weight-loss-associated improvement in glycemic control.

Several mechanisms have been proposed for this exciting and novel effect that may provide key insights
into the pathogenesis of type-2 diabetes. A range of novel surgical, endoluminal procedures/devices, and pharmacologic therapies are likely to evolve when we better understand how bariatric surgery enables long-term changes in energy balance and non-weight-related metabolic improvements. Bariatric surgery should be considered for adults with BMI > or = 35 kg/m² and type-2 diabetes, especially if the diabetes is difficult to control with lifestyle and pharmacologic therapy. Although all bariatric procedures produce exceptional results in the management of type-2 diabetes, the choice of procedure requires a careful risk-benefit analysis for the individual patient.113

There is currently a global pandemic of obesity and obesity-engendered comorbidities; in particular, certain major chronic metabolic diseases (eg, type 2 diabetes) which markedly reduce life expectancy and quality of life and that metabolic/bariatric surgery is a highly successful therapeutic option for obesity and diabetes.114,115,116

Ikramuddin found in his cost-effectiveness that bariatric surgery is not cost-effective over shorter time horizons, or if the negative quality-of-life impact of increased body mass index is ignored.116 Depending on the surgical procedure the effects are different. In the latest analyses by Inabenet 23,106 patients were investigated regarding the resolution of diabetes. The 12-month remission rate of diabetes was least for gastric banding (28%) compared with the other procedures (RYGB 62%, sleeve gastrectomy 52%, BPD/DS 74%).123

Quality of life after bariatric surgery

Various studies have shown that quality of life is improving after bariatric surgery in relation to weight reduction and improvement of comorbidities.117-122 Comparative studies between diabetics and non-diabetics are still missing, but various studies have shown that diabetes is rapidly improving with bariatric surgery and therefore improvement in Quality of Life is to be expected.

Quality of life in diabetic patients after bariatric surgery

In our own data we have been using prospective data from a group of total 524 patients which underwent bariatric surgery in between 2001 and 2005. The data were collected in an ongoing prospective longitudinal survey executed in a single center in Germany. All patients underwent standardized presurgical evaluation and all procedures were performed laparoscopically. Evaluation took place 1 day prior to surgery, after 1, 3, 6, 9, and 12 months, and then at yearly intervals. 3 standardized surgical procedures were performed: Adjustable Gastric banding, Roux-en-Y gastric bypass, and BPD-Scopinaro.

Table I
Measurement instrument for HRQL-overview

<table>
<thead>
<tr>
<th>Generic questionnaires</th>
<th>Diabetes-Specific questionnaires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Outcomes Study (MOS)</td>
<td>Diabetes Quality of Life (DQOL) measure</td>
</tr>
<tr>
<td>SF-36, SF-20, SF-12</td>
<td>Diabetes-39 instrument</td>
</tr>
<tr>
<td>QWB-SA</td>
<td>Problem Areas in Diabetes (PAID) Survey</td>
</tr>
<tr>
<td>Sickness Impact Profile</td>
<td>Diabetes Treatment Satisfaction Questionnaire (DTSQ)</td>
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<td>Nottingham Health Profile</td>
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Table II
Patient characteristics according to surgery type

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Banding</td>
<td>100</td>
<td>19.1</td>
</tr>
<tr>
<td>Gastric Bypass</td>
<td>355</td>
<td>67.7</td>
</tr>
<tr>
<td>BPD</td>
<td>69</td>
<td>13.2</td>
</tr>
<tr>
<td>Total</td>
<td>524</td>
<td>100</td>
</tr>
</tbody>
</table>
3) Diabetic patients with improvement of diabetes (patients, who indicated 1 at the non-QoL-scale of the BQL preoperatively and indicated 1 at 6 and 12 months, but did loose either their insulin or their or medication at one of the measurement points).

The lack of the study was that HbA1c levels were not conducted and that the assessment was sole done via the questionnaire. Furthermore no differentiation was made between Diabetes Mellitus Type 1 and Type 2. The retrospective control of this data is currently in process of work.

The data regarding type of surgery are displayed in table I.

As far as the majority of diabetes patients were in the bypass group, there was no differentiation made between the different types of surgery regarding the impact on diabetes, because the separate analysis would not create helpful results. The data regarding the subgroups are displayed in table II. Interestingly all patients with diabetes showed at least an improvement in diabetes after bariatric surgery.

All data were included with had full data (BQL score, SF-12 score, BAROS) available at all Measurement Times at 0,6 and 12 months of surgery. In total data from 286 patients could be included into the evaluation.

As far as that with the BAROS no pre-op data assessment is possible, we defined month 1 as first measurement point.

The Development of BMI is displayed in table III for the different subgroups. All groups had a significant weight loss achieved, there was no significant difference in BMI loss between the groups (fig. 1), so that the sole weight loss cannot be the explanation for the differences measured in Quality of Life in between the groups.

Regarding the evaluation of the Quality of Life in the diabetic patients we evaluated the applied 3 questionnaires according to the assigned groups and we did find with the BQL significant differences within the groups, especially between patients with remission and non-diabetics. (fig. 2). These results did not show significant correlation to the BMI loss, which emphasizes the fact that the sole BMI loss is not the course for the changes in QoL.

We could show, that obese patients seeking for surgery with Diabetes have a worse quality of life than non-diabetics, but that their quality of life improves with the resolution up to the level of non-diabetics. Moreover we could find a difference between patients in which the diabetes improved and the patients with remission, as far as their levels improve with time and

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No-preop diabetes</td>
<td>435</td>
<td>83</td>
</tr>
<tr>
<td>Diabetes in remission</td>
<td>44</td>
<td>8.4</td>
</tr>
<tr>
<td>Diabetes improved</td>
<td>45</td>
<td>8.6</td>
</tr>
<tr>
<td>Total</td>
<td>524</td>
<td>100</td>
</tr>
</tbody>
</table>

Table IV

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>BMI pre-op</th>
<th>BMI at 6 months</th>
<th>BMI at 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pre-op Diabetes (n = 180)</td>
<td>45.44 ± 7.8</td>
<td>36.36 ± 6.55</td>
<td>32.51 ± 6.01</td>
</tr>
<tr>
<td>Diabetes in remission (n = 26)</td>
<td>47.79 ± 6.0</td>
<td>38.20 ± 5.75</td>
<td>34.21 ± 6.06</td>
</tr>
<tr>
<td>Diabetes improved (n = 7)</td>
<td>47.3 ± 7.28</td>
<td>38.29 ± 5.76</td>
<td>35.46 ± 5.59</td>
</tr>
<tr>
<td>Total (n = 213)</td>
<td>45.79 ± 7.6</td>
<td>36.64 ± 6.45</td>
<td>32.81 ± 6.02</td>
</tr>
</tbody>
</table>

Fig. 2.—BMI loss within the subgroups.
weight loss, but they can not adapt to the level of non-diabetics. These findings are similar to what the experiences from the conservative diabetes treatment have shown, despite the fact that in conservative strategies the remission can not be achieved. Therefore it can be stated that with bariatric surgery obese diabetics profit even more from the surgery than non-diabetics. Regarding these finding it can probably expected that even non-obese diabetics might profit from bariatric surgery regarding their quality of life. Moreover these
results show, that the BQL is able to measure differences also for this specific issue.

Interestingly we could measure similar results with the MOS Short Form 12 (SF-12), but as expected from the above listed literature from the conservative diabetes treatment investigations the changes are not that strong. With these small numbers no significance could be shown between these groups, but it underlines the results of the BQL. Here again the differences between generic and disease-specific can be detected.

The most interesting result was the data of the applied BAROS (Bariatric Analysing and Reporting Outcome System) together with the MA-II questionnaire. Even slight differences similar to the results of the BQL and the SF-12 could be seen, but there could be no significance shown. This is probably due to the fact that the weight loss (measured in EWL in %) is part of the final result and gives to much impact on the outcome and therefore the BAROS is not able to detect the differences between the diabetics and non-diabetics.

Conclusions

Can quality of life in people with diabetes be improved?

Several studies describe medical interventions designed to improve health status in people with diabetes, and report assessments of impact on quality of life. Some of these studies implied that patients who had a decrease in HbA1c of 1% were associated with substantial decrements in quality of life, while decreases of the same magnitude showed smaller, but clinically relevant, improvements in quality of life.

Thus, it appears that health-related quality of life in people with diabetes can be improved by certain medical interventions and by educational and counseling interventions designed to enhance coping skills. However, it generally is difficult to know what aspect of the intervention is producing the change in quality of life because all relevant factors were not measured and incorporated into the analysis.

The improvement of glycemic control in diabetics is the leading pattern with regard to the improvement of Quality of Life in patients with diabetes type 1 and 2. Differences between these two groups could only be estimated with regard to age. In patients with surgical treatment (various procedures), of the metabolic syndrome quality of life can be improved in all diabetic patients in relation to their glycemic control and their weight loss. It seems that surgery has a stronger impact on the stabilization of the glycemic control in patients with either diabetes type 2 or type 1 than the medical treatments. The effect on the improvement of Quality of Life is more pronounced, when obesity is a coexisting entity. More comparative randomized controlled studies are mandatory to verify this encouraging perspective.

What can be concluded from the actual study?

From the literature it is evident that Quality of life is worse in the diabetic patient. We could show that diabetic patients with obesity have a worsened quality of life compared to obese non-diabetics, as far as no differentiation was made between Diabetes Type 1 and Type 2. QoL improves more in the diabetes patient with remission and/or improvement compared to the non-diabetic group. The better improvement in the diabetic patient is correlated to BMI loss, but the BMI loss does not explain the differences to the non-diabetes group. The BQL as a specific instrument is able to show these differences.

Further investigation needs to be done, regarding the impact and change of HbA1c levels and the resolution of co-related comorbidities (hypertension etc.)

References


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