

Editorial

Why a new journal and why call it *Infusystems Middle East*? The field of diabetes is covered by more than possible to read scientific journals, including insulin therapy.

However, clinicians and technicians using or working in the field of insulin infusions systems, i.e. pumps and related technologies e.g. sensors, needed a media capable of distributing practical and/or technical information. Indeed, information such as reports on side-effects, early pilot experience with a new model or technique, full description or comparison of products, administrative or legal information on pump treatment, e.g. reimbursement, usually can not appear in conventional scientific journals.

Twenty years ago, a French version of this journal was launched for French speaking readers: "**Infusystemes**". It has since become the reference journal on insulin pump technology in France. Four years ago, we began publishing and distributing in Europe its English speaking companion, *Infusystems International*, whose choice of authors and subjects was specifically made for the European readers. Three years ago, we launched *Infusystems USA* specifically made for the North American specialists. Two years ago, *Infusystems Latina* was launched for Spanish speaking specialists.

By its choice of topics, *Infusystems Middle East* will be directed specifically and distributed all across Asia to diabetologists interested in insulin infusion related technologies.

As founding members, the world-leading pump companies, that join the adventure as well as all editorial board members listed on this page, will all be consulted on a regular basis to provide new ideas and orientation for the journal. Of course, other pump related companies as well as individuals and colleagues who wish to participate actively in the journal are welcome to join us.

Most articles will be by invitation, but the journal will also welcome articles, technical notes, and short comments from the readers. There will be no peer-review process. articles need only be short (<8 pages, <10 references) and adjusted to the scope of the journal, i.e. have a practical impact on the practice of pump therapy (see instruction for authors at www.publiscripts.com).

Infusystems Middle East will be distributed quarterly and free of charge to approximately 2000 specialists across Asia. You are among them because you are known as being active in the field.

Please do not hesitate to send your comments, suggestions and/or criticisms to improve this journal and make it yours.

Prof. Jean-Louis Selam

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Insulin therapy and Continuous Subcutaneous Insulin Infusion Therapy (CSII) in the "New Diabetes World"

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This paper is supposed to offer insight into the latest and significant achievements of diabetes care (focusing on insulin and insulin pump therapy) of the Middle East including India from the perspective of a "western" endocrinologist based upon the individual practical experience acquired in the years from 2002 to 2005.

The enormous burden of diabetes mellitus in this geographical area (by far surpassing epidemiological data from any other region worldwide) will be described and defined later on. At this stage, it might be certainly necessary to define and explain the use of the term "New Diabetes World" in this manuscript in contrast to other terms used in publications on this topic, such as "Emerging Countries", "Emerging Diabetes Countries" or even "Developing countries". None of these descriptions are appropriate as far as the various cultural, socio-economic and diabetologic criteria are concerned. The easiest applicable difference refers to the socio-economic background as this area includes a huge economic portfolio ranging from very poor regions in India to very consolidated regions in the Middle East, even exceeding the limitations of common budget-restricted settings in the western world. On the other hand, although heterogeneously developed, there are countries whose acute response to the new emerging challenge in the field of diabetes care are so professionally thought-out by their national diabetes associations that they can easily com-

pare with their western counterparts. Finally, the very different cultural approach of social disease coping patterns, mainly influenced by well-defined familial structures and lack of hesitance to share responsibilities justifies as well to refuse the unfair use of the terms mentioned above and to rather describe this area as the "New Diabetes World", keeping in mind that the epidemiological numbers are exceeding by far comparable data of the rest of the world.

Epidemiology

The data released by the IDF and WHO (1,2) shows that the prevalence of diabetes for all age-groups worldwide was estimated to be 2.8 % in 2000 and 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. The top ranked country worldwide as far as absolute numbers are concerned is India (Figure 1) rather based upon their high population than on their also high incidence rate. As far as the relative prevalence is concerned, nearly the whole world ranges below a threshold of 8% (Figure 1) whereas the Middle East has been identified far beyond these numbers, revealing a rate of prevalence ranging from nearly 10%, e.g. in Egypt or Lebanon to as much as 25%, e.g. in Kuwait or the UAE (3-5). The latter reveals the highest prevalence of diabetes worldwide if the prevalence on the small Island of Nauru is ignored.

Moreover, in contrast to countries in

Europe for example where most people with diabetes are above the age of retirement, people in the Middle East are most often affected at the age between 35 and 64 which even multiplies the burden in terms of "Disability adjusted Life Years" (DALYs) and "Years Lived with Disability" (YLDs). Indeed, in some countries of the Middle East, one in four deaths in adults aged between 35 and 64 years is attributable to diabetes (6).

The most common explanation for this huge difference in prevalence in those countries is given by Alwan and King (7). These authors have invoked the "thrifty genotype" hypothesis to be potentially applied to this phenomenon. Populations that lived in formerly harsh environmental conditions, such as are found in much of the Middle East, have developed an efficient metabolism in order to better survive. This former advantage proves detrimental once a modern lifestyle, characterized by inactivity and a high-energy diet, is adopted. This hypothesis is further supported by national health surveys (Figure 2) like the one conducted in Australia (8) revealing that people born in the Middle East develop diabetes at a much higher rate than people of other origin.

These alerting numbers and figures provided by the WHO and the IDF have led to major projects in these regions, like e.g. the "Action Now" initiative (9) which is being spread by the local national institutions to improve diabetes care and to fight

naïve beliefs like the very common one that the glucotoxic complications of diabetes mellitus may not affect the local population as much as in other countries which, of course, has already been disproven by many international (see [6] for overview) and local studies (10).

Insulin therapy and CSII in the Middle East and India

In the following, general and specific aspects concerning the implementation of insulin therapy and insulin pump therapy (CSII) in these regions will be described. This individual report is part of a three-year-experience in the Middle East, being based in the UAE, and the fruitful cooperation with local colleagues whilst offering numerous insulin and CSII workshops in and with physicians from the UAE, Saudi-Arabia, Kuwait, Bahrain, Qatar, Oman, Yemen, Egypt, Libya, Lebanon, Syria, Jordan, Iran and India.

Aspects of insulin therapy in the Middle East and India

The implementation of diabetes care in general is going through the same processes and stages as in the west with one major difference: it is and has to be much faster than anywhere else due to the explosive development and incidence of diabetes. The major aspects are the same and follow the same sequence. First of all, the awareness is being raised by the health care professionals (a significant proportion of them highly experienced and/or with a history of training abroad) downstream to the level of general practitioners. Secondly, but mostly incomplete yet, the awareness is being raised to the population and the health authorities, always keeping in mind that the local identification of diabetes as a national health care problem usually dates back less than 20 years.

A major drawback of diabetes care and revealing an unbearable discrepancy compared to the actual patients' needs is the lack of diabetes nurses

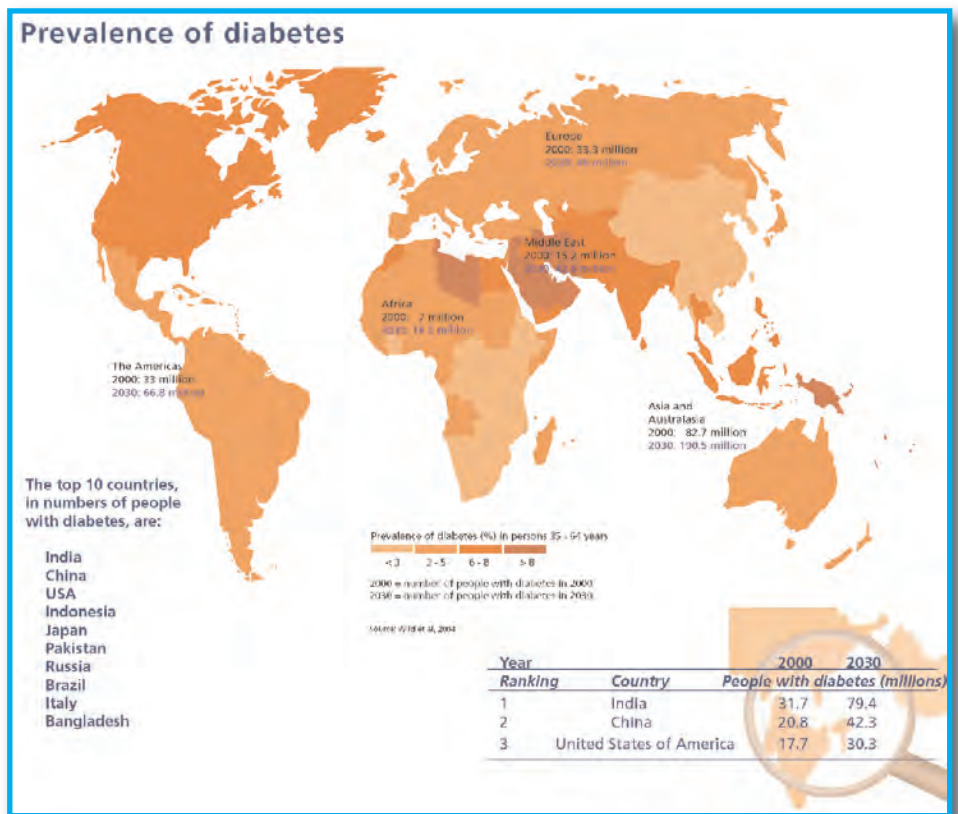


Figure 1 (with courtesy from the IDF Global Diabetes Burden Map)

and diabetes educators. Especially the lack of sufficient numbers of diabetes educators hinders the development of diabetes care and leaves the physician in a one-to-one situation every time he decides to start a patient on insulin therapy. For example in the UAE, the percentage of available trained diabetes educators does not exceed 10% of the estimated number needed to provide at least basic care. Hence, many of the professionally developed diabetes programs in these nations are stuck in the process because the staff requirements are not fulfilled. In contrast to the problem of physicians, recruitment of foreign diabetes educators is limited by the language problem and recruitment of local diabetes educators which have been trained abroad is limited by the very small number of locals that opt for a course as diabetes educator abroad. The only feasible mid-term solution for this problem is the initiation of local schools and training centers for diabetes educators and nurses.

Despite this inverse, top-heavy pyramid of diabetes care, the endocrinologists in this region are bravely taking the challenge to cover the needs by

interacting with their national governments and by having founded an international Gulf Diabetes Association.

Apart from these common systemic hurdles, there are further, more specific because cultural characteristics to be mentioned when describing diabetes care in the Middle East and the problems to initiate insulin therapy. As impressive and respectable the maintenance of the importance of familial bondages and mutual support may be, completely different situations may occur during the treatment of patients with diabetes, especially with insulin. In general, the percentage of patients on delayed oral therapy is still excessively high due to individual reasons aggravating the above mentioned features and leaving the average HbA1c mostly above 10%. For instance, insulin is much more associated with the well known "end-of-life"-scenario, increasing the resistance to insulin therapy. Whereas this might still be considered as a marker for the yet not sufficient work on public awareness of diabetes, many patients adamantly refuse insulin because of the social stigmati-

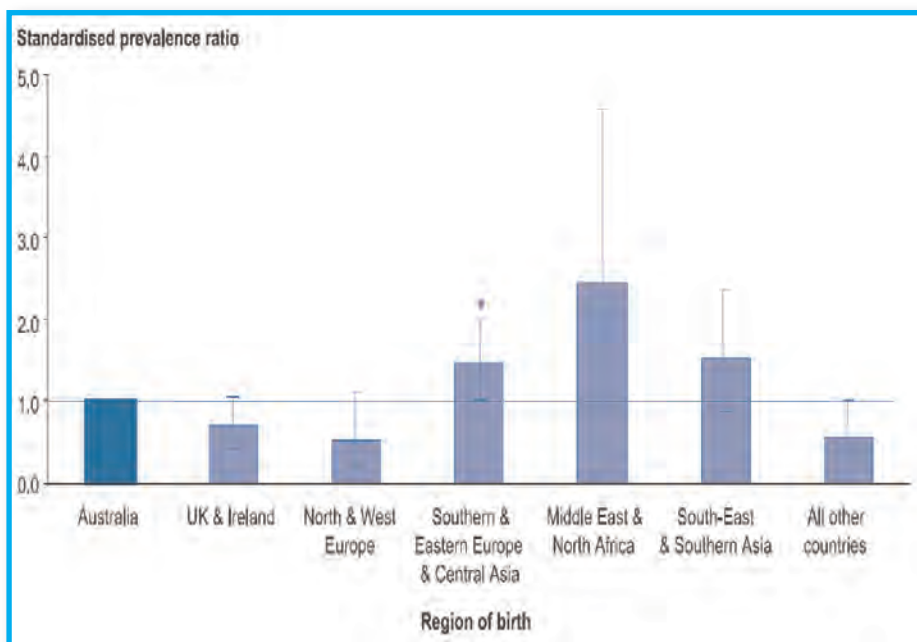


Figure 2: Standardised prevalence ratios for self-reported diabetes (females by birth-place), Australian National Health Survey 2001

sation (association with drug addiction) and the special semantic association of the Arabic word for syringe (ibre, pronounced "eebbre") that has been widely "abused" as educational threat in children. The hesitation, sometimes strict refusal, to use the abdominal region for injections is another typical feature, leaving the thigh and the non-favoured shoulder region as the only possibility for any injection or infusion therapy. Just in order to complete the picture, alternative traditional medicine and shaman medicine has to be mentioned as well although, apart from a minority of Bedouin population in some regions, they do not play a very significant role anymore because of the nationwide coverage with school medicine physicians.

Nevertheless, diabetes care is significantly improving in this region whereas each country reveals different prerequisites. Lebanon for example has a long-standing health care structure combined with training facilities for all levels of health care professionals and is certainly one of the most advanced nations in this region. Egypt as well benefits from a long history of independent university structures. Actually, the same applies to Iran but financial restrictions may be more significant.

Another very impressive health care structure can be found in Libya where physicians are extremely well trained and national diabetes programs are very advanced already. This might be true for the remaining Gulf region as well very soon but time is yet to short since these programs were able to start. Additionally, residency programs for Internal Medicine still have to be established there in order to prepare nationwide and complete diabetes programs.

The situation in India has to be described separately because of the significant differences. First of all, the characteristics are very heterogeneous as we are talking about a sub-continent as big as Europe with an estimated population of 1.3 billion. Secondly, the range between minimal care and comprehensive care is very wide. Furthermore, traditional medicine plays a very important role, somehow co-existing but not competing with school medicine. Levels of care differ very much in the different regions as well as between urban and rural areas. High levels of care are available in the bigger cities like New Delhi, Mumbai (former Bombay) and Chennai (former Madras) or Kochi in the region of Kerala. The latter, for example, is very famous in the whole eastern hemisphere for their well-

trained nurses. The organisation of diabetologists and endocrinologists is very advanced in India. Beside the universities looking back on a long tradition, several major endocrine clinics with associates are available in the bigger cities being very active in clinical work and research. Moreover, in those centres, tremendous efforts are put into public relation work to increase awareness. Patients themselves differ from the Middle East very significantly by being classified as overweight if BMI is over 22 already and obese if BMI is over 25. Moreover, patients with diabetes in India certainly reveal another subgenotype out of the "type 2 syndrome" with a rapid loss of insulin secretion and very high prevalence of insulin resistance.

Finally, it is quite interesting how fast India was able to adopt to the situation of facing an urgent need of implementing diabetes care on one hand side and taking advantage of the unique legal background for copyrights on the other hand by already producing their own generic insulins and their own generic glucometers. It is not quite clear yet how much this will only serve the local problem or even interfere with global industrial interests.

Aspects of insulin infusion therapy (CSII) in the Middle East and India

As far as CSII is concerned, there was a very comparable situation available in all these countries in terms of only very limited and individual experience with insulin pump therapy. Hence, all the CSII workshops were more or less launching insulin pump therapy in these countries. Nearly the whole region is covered by one insulin pump distributor who is based in Beirut as far as the Middle East is concerned and in New Delhi as far as India is concerned. Only casuistically, far eastern pump products were available in India but did not succeed because of lack of support. With the proviso that professional diabetologic expertise was already

available as mentioned above but practical translation was limited due to the small number of diabetes educators, CSII could be implemented very rapidly but for a small number of selected patients only. A main focus of CSII introduction was the importance of separation of basal and bolus algorithms as intensified insulin therapy is largely under-represented. Whereas bolus algorithms were just transferred from injection therapy to CSII as usual, adaptation of basal algorithms had to be trained intensively. Despite the fact that the initial situation was not comparable at all to our well known scenarios, CSII was very successfully introduced with the professional support of local health care professionals attending the workshops and the self-understanding fact but worthwhile mentioning that patients did well although many of them had to upgrade their diabetes therapy from a minimal insulin care without previous extended diabetes education to CSII accompanied with intensive diabetes education in a very short time. This has to be explained in detail, as it is not the typical approach in western countries where, e.g. in Europe, initiation of CSII is limited only to patients who have failed on intensive insulin therapy in order to keep diabetes care costs within the limits given by the budgets. The situation in the Middle East and India in the year 2002 was completely different. First of all, the whole region was actually naïve to insulin pump therapy. In other words, there were many patients already who really had a strong indication for CSII and did not have to prove the indication unnecessarily again on another insufficient regime. Secondly, many patients were able to finance the pump therapy on their own and were just rating the individually perceived "quality of life"-advantages higher than the potential metabolic equivalence of therapies. Last but not least, referring again to the very strong social impact of syringes, a huge proportion of patients, especially children and adolescents, revealed a much higher adherence to and acceptance of

insulin therapy after starting on the pump. This fact is mainly responsible for the fact that average HbA1c was extremely high in some pediatric centers before initiation of pump therapy, the highest average HbA1c reported was 14,3%! Especially in these areas, the initiation of CSII in the years from 2002 to 2005 was associated with a tremendous improvement of diabetes care in type 1 patients.

All in all, these examples show that the initiation of CSII in this region was quite significant from our western scenarios, especially as far as the decision to indicate the pump was concerned. On the other hand, this development will follow a natural S-curve reaching a saturation phase and all these special indications will be covered very soon. It is a very important task not to miss that point by constantly assessing the quality of indicating and performing CSII in this region.

Again, India has to be described separately because CSII launched there later and only a few patients were on a pump in 2005. Nevertheless, it was an impressive personal experience to accompany the first patients on CSII on the Indian subcontinent and especially to witness and consult on the first Indian baby born after "CSII-pregnancy". Perhaps this is a nice picture and anecdote to close with. The young mother without any school education or any diabetes education before dealt with the pump as professional as one could and she was managing basal and bolus algorithms in a fascinating way. This is in coincidence with a National Diabetes Survey in Libya (personal communication) where illiterate patients revealed a better diabetes control than all other parts of the population.

Summary

This rather descriptive paper was meant to describe the characteristics of diabetes care focusing on insulin therapy and CSII as perceived by a temporary guest in the Middle East and India from 2002 to 2005 and to highlight the huge burden of diabetes

in this region of the world that even exceeds all scenarios in the western world.

In face of all these difficulties, it is quite impressive how active and dedicated a, compared to the huge amount of emerging patients and the yet insufficient official support, rather small group of endocrinologists and diabetologists are trying to improve diabetes care in this region in order to cushion the blow of the predictable consequences of diabetes in their countries in the near future.

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Continuous Subcutaneous Insulin Infusion Therapy in Turkey

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Diabetes In Turkey: Actual State

Diabetes is a growing public health burden and also of a big health concern in Turkey, which has a population of nearly 75 millions. Turkish Diabetes Epidemiology Project (TURDEP), a cross-sectional, population-based survey showed that the crude prevalence of diabetes is 7.2% in the population aged >20 years (1). If the results of TURDEP Study are extrapolated to the general population in Turkey, the prevalence of diabetes is approximately 3.6%. This rate is higher than world average.

According to the findings of the nationwide Turkish Diabetes Chronic Complications Study the mean HbA1c is 8.6% in diabetic population. There are regional differences in the quality of diabetes care and they are prominent between the industrialized Western and Northwestern regions and the Eastern and Southeastern Anatolia with its economical and social problems. The rate of chronic complications is also higher in the Eastern regions than in the Western regions of Turkey (presented at the XXXIX.National Diabetes Congress, Istanbul, Turkey, 2003).

The V. Meeting at the X. Anniversary of St. Vincent Declaration was realized in Istanbul in the year 1999. Because the targets are not met at the Xth year Istanbul

Declaration is prepared. Following this event, the improvement of quality of diabetes care and the management and decreasing the prevalence of related chronic complications was seriously put on the agenda. According to newly established National Diabetes Program, nationwide programs are arranged for diabetes education and for new approaches in diabetes treatment. To reach the ideal HbA1c goals use of intensive insulin therapy protocols is started not only in the main universities but is generalized nationwide. In Turkey, the use of continuous insulin infusion systems and pumps has had an important place in diabetes treatment in the last 5 years but their reimbursement has only started in 2005.

Importance of Continuous Subcutaneous Insulin Infusion Systems

Today, although the targets for metabolic control are much lower than in the past introduction of several new drugs, improved delivery systems, easy applicable home blood glucose monitoring make them achievable. The acme in insulin treatment is to mimic completely its physiological secretion. Currently, the ideal way to reach the HbA1c goal is the Continuous Subcutaneous Insulin Infusion (CSII). There are two reasons for the use of basal-bolus insulin delivery protocols:

1. Current treatment protocols with new long-acting insulin analogues (Glargine, Levemir) cannot precisely simulate the physiological basal insulin secretion. Additionally insulin delivery cannot be precisely adjusted to meet changes in basal insulin need during the 24 hour period. Basal secretion is approximately 50% of total insulin and is higher during the daytime than in the nighttime. With continuous insulin infusion system, there is a possibility to mimic to some extent the physiologic basal insulin delivery and to adapt more easily to its 24-h diurnal rhythm.

2. In bolus insulin administration with Multiple Daily Insulin Injections (MDII) the onset, duration and peak time do not precisely overlap the postprandial blood glucose changes. The coverage of these changes is easier with bolus insulin pulses. Additionally, according to the amount and the frequency of carbohydrate intake, insulin delivery is not limited to 3 times.

Intensive insulin therapy has been shown to be clearly superior to conventional treatment in achieving tight metabolic control and reducing the risk of microvascular complications. But, strict metabolic control with classic MDII is associated with an increased risk of severe hypoglycemic episodes. Intensive insulin regimen with long-acting analogues; insulin glargine or insulin detemir in combination with rapid-acting

insulin analogues at meals reduce the frequency of hypoglycemia and maintain glycaemic targets (2). But, it is still far away from mimicking the physiological insulin secretion.

Insulin Pumps In Turkey

Insulin pumps have been used since the late 1970s. Data estimate that more than 162.000 people in the United States and 200.000 people worldwide manage their diabetes with CSII (3).

Insulin pumps were used approximately 15 years locally in some big Centers in Turkey. It is discontinued due to the similar outcomes of MDII and CSII because of some technological impediments and application failures.

With the introduction of new generation insulins and infusion pumps, their use started again in Turkey five years ago. Minimed-Medtronic and DanaDiaBeCare are two companies on the Turkish market. Other brands are expected to enter the market in the year 2007.

Currently there are approximately 600 insulin pump users. Among these patients 99.5% have type 1

diabetes. Male/female ratio is 42.5/57.5%. The distribution of pump users according to age shows a big variability ranging from 3.5 to 70 years.

The application of insulin pumps are mainly in Diabetes Centers of 6 Universities mostly located in three metropolitan cities (Istanbul, Ankara, Izmir) out of approximately 72 University hospitals.

ADRI Clinical Experiences

In Arateus Diabetes Institute (ADRI), where the largest serie of Turkish insulin pump users are followed, there are 41 patients (F/M 20/21) on insulin pump therapy. Age of the cohort is 32.1 ± 15.1 years (mean \pm SD) with a range of 9 to 74 years. Among these 41 patients, 38 have type 1 diabetes and 3 have type 2 diabetes with a mean diabetes duration of 13.2 ± 10.3 years (1-43 years). The overall follow-up period under insulin pump therapy is 14.7 ± 11.1 months (range 2-35 months). Routinely both basal rate and prandial boluses of the insulin are applied according to the results of frequent self-monitoring of plas-

ma glucose performed by a means of glucose meter (4-8 measurements per day) or continuous glucose monitoring system (CGMS) for reaching optimum diabetes control. To avoid hypoglycemic episodes and technological problems, every patient is given an educational period of 3 days with 0.9% saline infusion before initiating CSII. This period serves for getting used to the pump and its disposables. The dose adjustment and carbohydrate counting training are given to the patient mostly together with the family.

The HbA1c is significantly decreased with the insulin pump therapy ($7.7 \pm 1.7\%$ vs $7.4 \pm 1.2\%$, $p < 0.01$) and there is no change in body weight before and after pump therapy (64 ± 13.9 kg vs 65.5 ± 14.8 kg, NS) (4). These data are well correlated with the studies in the literature (5,6).

Most of the patients report flexibility of lifestyle and hence quality of life and treatment satisfaction in parallel with reductions in HbA1c level and hypoglycemic rate. But for the early pubertal or pubertal group in whom the compliance with the therapy is more difficult to achieve,

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inconsistent meals and boluses might counterbalance the advantage of the better basal insulin replacement offered by CSII.

Patients on insulin pump had significantly lower rates of severe hypoglycemia compared with those on regular insulin therapy and analogues. The use of CSII leads to a lower insulin requirement compared to the MDII (5).

Problems and Land of Promise of CSII

The main impediment for the insulin pump therapy in Turkey is the difficulties in reimbursement which was started in 2005. Patients have to apply to the University Hospitals or to the Governmental Hospitals with an endocrinologist. They have to obtain a report from the Health Authority (Board) of that Hospital for using the insulin pump. With this report, the health insurance covers a certain amount of the pump cost whatever the brand is, an done box of the infusion set and of the reservoir monthly. For pediatric/pregnant patients who should change the sets every other day this should be stated in the report.

Also, the number of endocrinologist is not sufficient in Turkey and the CSII systems are unfamiliar for diabetes care providers who may have hesitations to utilize the novel tech-

nologies in general. On the other hand there is a psychological resistance of patients against wearing an external device, being dependent on a device, which gives them the sensation of being different than the others and feeling the pump as a constant reminder of the diabetes. The prevalence of discontinuation of pumps is approximately 15% yearly. In spite of these, the number of patients using insulin pumps is increasing every day in Turkey.

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