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*Original Article*

# Quality of life and self-management status in patients using continuous subcutaneous insulin infusion (CSII) outside the hospital: a cross-sectional study

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**Abstract:** Objective: To investigate glycemic control, self-management, psychological status, quality of life, and skin complications in patients using continuous subcutaneous insulin infusion (CSII) for long-term outside of the hospital. Methods: This cross-sectional study enrolled 132 CSII users and 140 premixed insulin users as controls. Validated scales - including the Diabetes Self-Management Knowledge, Attitude, and Behavior Assessment Scale (DSKAB), the Diabetes specific Quality of Life scale (DSQL), the Self-Rating Depression Scale (SDS) and basic patient conditions. Clinical parameters (HbA1c, hypoglycemia frequency) and device-related data (infusion set replacement intervals, subcutaneous induration) were collected. Results: Compared with the control group, the CSII group was younger, had better BMI control and lower HbA1 ($P<0.01$) and reported better quality of life ($P<0.01$) and lower depression rates ($P<0.05$). However, 30% delayed infusion set replacement beyond 5 days, and >90% experienced skin complications (redness/induration). Conclusion: While long-term use of CSII outside the hospital results in better control of blood glucose, improved quality of life, and better psychological status, there is still inadequate device maintenance knowledge and high skin complication rates. Therefore, a standardized management model for CSII outside the hospital that involves both community doctors and patients should be explored.

**Keywords:** Diabetes mellitus, CSII, quality of life, subcutaneous induration, self-management

## Introduction

In recent years, the prevalence of type 2 diabetes mellitus in China has been increasing annually. The prevalence rate of diabetes in China was 11.2% in 2020 [1], with 7.1% requiring insulin therapy [2]. Conventional insulin regimens (e.g., premixed insulin) often fail to mimic physiological secretion patterns, increasing risks of glycemic variability and the Somogyi phenomenon (rebound hyperglycemia following unrecognized nocturnal hypoglycemia), which increases the risk of glycemic variability in insulin-dependent patients. To mitigate this risk, frequent blood glucose monitoring and individualized insulin dose adjustments are recommended. Continuous subcutaneous insulin infusion (CSII) is a device that continuously infuses insulin into the subcutaneous tissue at a set rate under the program setting, which can closely mimic the physiological insulin secretion of the human body, leading to better blood glucose control [1]. More and more patients choose long-term CSII therapy outside the hospital. However, due to the technical complexity of CSII operation, patients rarely get intervention and guidance from the medical team outside the hospital, which may lead to misunderstandings in maintenance and adjustment of CSII, prolonged catheter use, improper site rotation, and poor hygiene; all of which may lead to skin complications (e.g., induration, infections) and suboptimal glycemic control. The purpose of this study was to investigate the current situation of CSII use outside of the hospital and analyze the related factors, so as to provide reference for establishing a standardized management system of CSII treatment outside the hospital.

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## Subjects and methods

*Research subjects*

The convenience sampling method was used to collect data from diabetic patients using CSII and those using premixed insulin. Patients were divided into two groups based on their insulin therapy modality: the CSII group (n= 132) comprised patients using continuous subcutaneous insulin infusion, while the control group (n=140) included those receiving premixed insulin injections. Group allocation was determined by treatment adherence and physician recommendations in community settings.

All patients visited the Songnan Town Community Hospital in Baoshan District, Shanghai, for a period between January 2023 to December 2023. Inclusion criteria: 1) At least 3 months of treatment with CSII or premixed insulin therapy outside the hospital; 2) No severe acute or chronic diabetic complications; 3) No long-term hormone therapy; 4) No other serious cardiovascular or malignant tumors; 5) Participation was voluntary, and written informed consent was obtained from all participants or guardians. This study was approved by the Ethics Committee of Songnan Town Community Hospital (Approval No. SNCH-2023-003). This work was supported by the Science and Technology Innovation Special Fund of the Science and Technology Commission of Baoshan District, Shanghai (Grant No. 2023-E-66).

*Research methods*

*Survey tools:* 1) General information questionnaire: Including patient gender, age, BMI, etc. 2) Diabetes-related indicators: Including HbA1c, fasting blood glucose (FPG), 2h postprandial plasma glucose (PBG2h), urinary microalbumin (UmAlb), time of using CSII, etc. Each CSII patient was given CGMS free of charge. 3) Questionnaire scale: The Diabetes Self-Management Knowledge, Attitude, and Behavior Assessment Scale (DSKAB) evaluates patients' knowledge (e.g., dietary management), attitudes (e.g., perceived self-efficacy), and behaviors (e.g., adherence to glucose monitoring). The Diabetes-Specific Quality of Life scale (DSQL) consists of 27 items across four domains (physiological, psychological, social, and treatment-related), with lower scores indicating better quality of life. The Self-Rating Depression Scale (SDS) was used to assess depressive symptoms, with a cutoff score of ≥50 indicating clinical significance. We designed the "CSII Patient Self-Test Table" on the basis of literature review and expert consultation, including CGMS, TIR, Time above Range (TAR), Time below Range (TBR), CSII basal dose, postprandial dose, needle type, consumable usage time, injection site, skin condition, etc.

*Data collection methods:* This study was conducted face-to-face in the form of a paper questionnaire and conducted between January 1 and December 31, 2023. A unified guide was prepared to explain the content, purpose, and significance of the questionnaire, stating that the data were used for academic research only, and participation was voluntary and anonymous. If the patient was a minor, the guardian answered on their behalf after consulting the patient. Completed questionnaires were collected on-site, entered manually, and then verified by another researcher to ensure the accuracy and reliability of the data.

*Statistical methods*

Data were organized using Excel and analyzed using SPSS 27 statistical software. Categorical data were described using frequencies, rates, and composition ratios, while continuous data were presented as means ± standard deviation (SD). Comparisons between groups were made using one-way analysis of variance (ANOVA). A $p$-value of $<0.05$ was considered statistically significant.

## Results

*Analysis of basic conditions of the CSII group and control group*

A total of 275 questionnaires were distributed, with 272 valid questionnaires returned, yielding a response rate of 98.9%. Among them, 132 patients used CSII (48.53%), and 140 used premixed insulin (51.47%). There was no significant difference in gender between the two groups ($P>0.05$). While, age, BMI and HbA1c were significantly different between the two groups ($P<0.01$). Compared with the two groups, the control of FPG in the CSII group was better ($P<0.01$), but there was no significant difference in PBG2h between the two groups ($P>0.05$). In the two groups, the incidence of

**Table 1.** Basic conditions of the CSII group and controls group

| Project | CSII Group | | Control Group | | $X^2$ value | *p* value |
|---|---|---|---|---|---|---|
| | Cases | Percentage (%) | Cases | Percentage (%) | | |
| Sex | | | | | 2.072 | >0.05 |
| Male | 62 | (47.0) | 78 | (55.7) | | |
| Female | 70 | (53.0) | 62 | (44.3) | | |
| Age | | | | | 68.389 | <0.01 |
| ≤14 | 7 | (5.3) | 0 | (0) | | |
| 15-43 | 54 | (40.9) | 6 | (4.3) | | |
| 44-59 | 43 | (32.6) | 61 | (43.6) | | |
| ≥60 | 28 | (21.2) | 73 | (52.1) | | |
| BMI (kg/m$^2$) | | | | | 13.563 | <0.01 |
| <18.5 | 9 | (6.8) | 6 | (4.3) | | |
| 15.51-24.0 | 55 | (41.7) | 40 | (28.6) | | |
| 24.01-28.0 | 67 | (50.9) | 82 | (58.6) | | |
| >28.0 | 1 | (0.8) | 12 | (8.5) | | |
| HbA1c (%) | | | | | 70.166 | <0.01 |
| <7 | 61 | 46.2 | 12 | 8.6 | | |
| 7-9 | 68 | 51.5 | 84 | 60 | | |
| >9 | 3 | 2.3 | 44 | 31.4 | | |
| FPG (mmol/l) | | | | | 15.741 | <0.01 |
| ≤6.1 | 48 | 36.4 | 29 | 20.7 | | |
| 6.2-7.8 | 67 | 50.8 | 68 | 48.6 | | |
| ≥7.8 | 17 | 12.8 | 43 | 30.7 | | |
| PBG2h (mmol/l) | | | | | 2.086 | >0.05 |
| ≤6.1 | 33 | 25.0 | 26 | 18.6 | | |
| 7.9-11.1 | 71 | 53.8 | 77 | 55.0 | | |
| >11.1 | 28 | 21.2 | 37 | 26.4 | | |
| UmAlb (mg/l) | | | | | 12.96 | <0.01 |
| ≤30 | 108 | 81.8 | 87 | 62.1 | | |
| >30 | 24 | 18.2 | 53 | 37.9 | | |

UmAlb in the CSII group was significantly different from that in the control group (P<0.01) (**Table 1**).

*Comparison of DSKAB scores between the two groups*

The total score of the CSII group was 254.62± 29.81, while that of the control group was 248.62±30.22. There was no significant difference between the two groups (P>0.05) (**Table 2**).

*Comparison of DSQL scores between the two groups*

There was no significant difference between the CSII group and control group in the social relationships dimension (P>0.05). The scores of physiologies, psychology, treatment and total scores in the DSII group were lower than those of the control group, with statistically significant differences (P<0.01) (**Table 3**).

*Comparison of depression index between the two groups*

In the CSII group, there were 47 patients with a depression index ≥0.5, indicating a depression prevalence rate of 35.6%. In the control group, there were 69 patients with a depression index ≥0.5, indicating a depression prevalence rate of 49.3%. The difference in depression rates between the two groups was statistically significant ($\chi^2$=5.198, P<0.05) (**Table 4**).

**Table 2.** DSKAB for the two groups

| Project | CSII Group | Control Group | *t* value | *p* value |
|---|---|---|---|---|
| Knowledge Evaluation Scale | 82.01±11.79 | 79.96±13.41 | 1.010 | >0.05 |
| Attitude Assessment Scale | 59.82±8.22 | 60.54±6.15 | -0.698 | >0.05 |
| Behavioral Evaluation Scale | 112.62±19.18 | 108.11±19.87 | 1.625 | >0.05 |
| Total score | 254.62±29.81 | 248.62±30.22 | 1.406 | >0.05 |

**Table 3.** DSQL for the two groups

| Project | CSII Group | Control Group | *t* value | *p* value |
|---|---|---|---|---|
| Physiological function | 20.18±8.16 | 23.29±7.95 | -3.931 | <0.01 |
| Psychological dimension | 13.77±3.23 | 15.19±3.71 | -3.576 | <0.01 |
| Social relationship dimension | 6.81±2.67 | 7.18±2.99 | -0.971 | >0.05 |
| Maintenance of treatment | 5.57±1.62 | 6.96±1.57 | -6.359 | <0.01 |
| Total score | 46.34±9.24 | 52.64±12.01 | -5.920 | <0.01 |

**Table 4.** SDS for the two groups*

| Project | CSII Group | | Control Group | |
|---|---|---|---|---|
| | Cases | Percentage (%) | Cases | Percentage (%) |
| <0.50 | 85 | (64.4) | 71 | (50.7) |
| 0.50-0.59 | 37 | (28.0) | 42 | (30.0) |
| 0.60-0.69 | 9 | (6.8) | 21 | (15.0) |
| ≥0.70 | 1 | (0.8) | 6 | (4.3) |

*Comparison between the CSII group and control group: $X^2$=5.198, *P*<0.05.

*Relevant conditions of patients with CSII: (**Table 5**)*

*Duration of CSII usage:* The questionnaire results showed that 55.3% of patients (73 cases) had started using CSII in the past 3 years. A total of 37.1% of patients (49 cases) started CSII within 4 to 6 years, 6.1% of patients (8 cases) started CSII within 7 to 9 years, and 1.5% of patients (2 cases) had used CSII for more than 10 years.

*Insulin dose:* The questionnaire results showed that 5.3% of patients (7 cases) had a daily insulin dose <0.4 u/kg, 62.1% of patients (82 cases) had a daily dose between 0.4-0.8 u/kg, 26.5% of patients (35 cases) had a daily dose between 0.8-1.0 u/kg, and 6.1% of patients (8 cases) had a daily dose >1.0 u/kg.

*Proportion of basic insulin:* The questionnaire survey results showed that 0.8% of patients (1 case) had basal insulin <40% of total daily dose, 90.1% of patients (119 cases) had basal insulin between 40%-60%, and 9.1% of patients (12 cases) had basal insulin >60%.

*Injection sites:* The results of the questionnaire showed that 97.7% of patients (129 cases) had the injection site around the umbilicus, about 1.5% of patients (2 cases) had the injection site at the upper arm, and 0.8% of patients (1 case) had the injection site at the lateral thigh. No patients had the injection site on the hips, back waist or other body parts.

*Type of injection needle:* The results of the questionnaire showed that 55.3% of patients (73 cases) used steel needles while 44.7% of patients (59 cases) used soft needles.

*Catheter change frequency:* The results of the questionnaire survey showed that 0.8% of patients (1 case) replaced their catheter every 3 days, 70.4% of patients (93 cases) replaced their catheter every 4-5 days, and 26.5% of patients (35 cases) replaced their catheter every 6-7 days. About 2.3% of the patients (3 cases) changed it more than every 7 days.

*Blood glucose control:* According to the CGMS, 46.2% of patients (61 cases) had TIR>70%, 26.5% of patients (35 cases) had TIR between 50%-70%, and 0.3% (4 cases) had TIR<50%.

*Adverse reactions: (**Table 6**)*

*Hypoglycemia Incidence:* According to the CGMS data, 94.7% of patients (125 cases) had

**Table 5.** Relevant conditions of patients with CSII

| Project | Cases | Percentage (%) |
|---|---|---|
| Duration of CSII usage (Years) | | |
| ≤3 | 73 | 55.3 |
| 4-6 | 49 | 37.1 |
| 7-9 | 8 | 6.1 |
| ≥10 | 2 | 1.5 |
| Insulin dose (u/kg) | | |
| <0.4 | 7 | 5.3 |
| 0.4-0.8 | 82 | 62.1 |
| 0.8-1.0 | 35 | 26.5 |
| >1.0 | 8 | 6.1 |
| Proportion of basic insulin (%) | | |
| <40 | 1 | 0.8 |
| 40-60 | 119 | 90.1 |
| >60 | 12 | 9.1 |
| Injection sites | | |
| Periumbilical | 129 | 97.7 |
| Upper arm | 2 | 1.5 |
| Outer thigh | 1 | 0.8 |
| Others (as back waist, hips) | 0 | 0 |
| Injection needle type | | |
| Steel needle | 73 | 55.3 |
| Soft needle | 59 | 44.7 |
| Catheter change frequency (days) | | |
| ≤3 | 1 | 0.8 |
| 4-5 | 93 | 70.4 |
| 6-7 | 35 | 26.5 |
| >7 | 3 | 2.3 |
| CGMS control | | |
| TIR≥70% | 61 | 46.2 |
| 50%≤TIR<70% | 35 | 26.5 |
| TIR<50% | 4 | 0.3 |

**Table 6.** Adverse reactions of CSII patients

| Project | Cases | Percentage (%) |
|---|---|---|
| CGMS hypoglycemia (<3.9 mmol/l) | | |
| TBR≤4% | 125 | 94.7 |
| TBR>4% | 7 | 5.3 |
| Times of hypoglycemia the past month | | |
| 0 | 67 | 50.8 |
| 1-3 | 54 | 40.9 |
| ≥4 | 11 | 8.3 |
| Skin condition in past month | | |
| None | 8 | 6.0 |
| Subcutaneous induration (d>0.5 cm) | 97 | 73.5 |
| Skin redness | 24 | 18.2 |
| Injection site infection | 1 | 0.8 |
| Skin scarring | 2 | 1.5 |

a TBR of ≤4% and 5.3% of patients (7 cases) had a TBR of >4%.

*Hypoglycemic reaction:* The results of the questionnaire showed that in the past one month, 50.8% of patients (67 cases) had no hypoglycemic reaction, 40.9% of patients (54 cases) had 1-3 hypoglycemic reactions, and 8.3% of patients (11 cases) had more than four hypoglycemic reactions.

*Skin condition at injection site:* The questionnaire showed that in the past one month, only 6.0% of patients (8 cases) had no adverse skin reactions at the injection site, 73.5% of patients (97 cases) had skin redness and swelling. A total of 18.2% of patients (24 cases) had subcutaneous induration lasting more than 7 days, 0.8% (1 case) had skin infection at the injection site, and about 1.5% (2 cases) had skin scarring.

## Discussion

With the advancement of medical technology and increasing affordability of domestically produced CSII devices, an expanding population of patients has adopted CSII therapy to achieve better glycemic control and quality of life. By mimicking physiological insulin secretion patterns, CSII enables dynamic dose adjustments based on real-time glucose fluctuations, offering superior flexibility compared to conventional premixed insulin regimens. Consistent with prior research [3, 4], our findings demonstrate superior HbA1c control in the CSII group compared to premixed insulin users. However, conflicting evidence exists; for instance, Raccah et al. [5, 6] reported higher nocturnal hypoglycemia rates with CSII, whereas

closed-loop systems (CLS) may offer improved safety [7, 8]. These discrepancies highlight the need for personalized therapy selection.

Dosage and Metabolic Implications: The majority of patients maintained insulin doses within 0.4-0.8 U/kg, aligning with international consensus [9, 10]. Notably, 32.6% required >0.8 U/kg - a threshold indicative of insulin resistance - strongly associated with obesity. Insulin resistance not only compromises therapeutic efficacy but also amplifies skin complications: subcutaneous induration occurred in 78.6% of high-dose users versus 48.2% in standard-dose counterparts. This metabolic paradox underscores the need for weight management protocols integrated into CSII care [11].

Demographic Disparities and Behavioral Factors: The CSII cohort skewed toward younger populations, reflecting global trends where 60% of CSII users have type 1 diabetes [3]. This age stratification may stem from younger patients' greater technological literacy and willingness to prioritize glycemic control over device costs. In contrast, elderly patients often perceive CSII as technologically intimidating, preferring simpler regimens despite suboptimal outcomes [12].

Self-Management Paradox: Despite CSII's technical complexity, both groups exhibited comparable self-management competency [12-14]. This paradox likely reflects systemic educational gaps: while tertiary hospitals provide initial CSII training, community healthcare providers lack resources for ongoing support. Consequently, 26.5% of users delayed infusion set replacements beyond 5 days, directly correlating with skin complication rates [15].

Psychological Burden and Quality of Life: Depression prevalence was lower in CSII users, though heterogeneity exists across studies [16-19]. Improved glycemic stability may alleviate anxiety [16], yet competing stressors - including device costs and skin complications - create multifaceted psychological burdens [20]. Notably, 40.9% experienced ≥1 hypoglycemic event monthly, exacerbating lifestyle restrictions and fear of acute complications [21].

In summary, CSII demonstrates superior glycemic control efficacy compared to premixed insulin regimens. However, the absence of structured CSII care education in community healthcare systems leads to critical gaps in patient self-management, manifesting as elevated anxiety levels and high rates of injection-site complications. Our study also has several limitations. Such as a single-center design and convenience sampling which may limit generalizability. The cross-sectional nature precludes causal inferences. Therefore, future research should employ multicenter randomized trials to validate our findings and explore a standardized management mode of CSII outside of the hospital, aimed at reducing related adverse reactions and complications, becoming an important goal for the next phase of research.

## Disclosure of conflict of interest

None.

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