Evaluation Of Glycaemic Control Using Insulin Pump Therapy In "Poor" Candidates And Non Insured Children In A Rural Diabetic Youth Clinic

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Background

Australian children with Type 1 Diabetes Mellitus (T1DM) are currently denied access to Insulin Pump Therapy (IPT) for three main reasons:

1.Lack of funds - most Australian children gain access to an insulin pump through private health insurance. Those without insurance cannot usually afford to purchase an insulin pump.

2.Not considered a "good" candidate" for IPT - they fail to fulfill a number of traditional prerequisites and are therefore neither offered nor encouraged to trial IPT.

3.Lack of local resources - patients have difficulty accessing an experienced insulin pump team, particularly in rural Australia.

Our rural based multidisciplinary team has demonstrated that successful insulin pump therapy can be initiated and maintained in rural Australia using local resources. (1) Our rural diabetic youth have experienced significant improvement in glycaemic control, quality of life and very high levels of patient satisfaction.

There is scant data to determine whether children and adolescents who are usually denied access to IPT for the reasons other than lack of local resources would benefit from IPT. One study of adult uninsured T1DM patients demonstrated no improvement in glycaemic control. (2)

Some studies have demonstrated that the greatest improvement in HbA1c using IPT is in those with poor glycaemic control. (3) The DCCT demonstrated that the greatest risk of long term complications from T1DM occurs with poor glycaemic control. (4) Yet there is little support of considered selective management of children with very poor glycaemic control with IPT.

Aim

To evaluate the effect of Insulin Pump Therapy (IPT) on glycaemic control in children traditionally considered as "poor candidates" or without health insurance.

Methods

Gippsland Paediatrics services a regional South Eastern Australia population of 95,000 people. The population is representative of a typical rural Australian population. Our diabetes team manages over 90% of children and adolescents (up to 25 years of age) with T1DM in the region.

An observational study of 70 T1DM patients was performed to analyze the glycaemic outcome over the first 2 years of IPT in "good" vs. "poor" candidates and insured vs. uninsured patients.

An eligible patient was any patient managed by Gippsland Paediatrics with insulin pump therapy between 2007 and 2011 inclusive.

1. "Poor" candidates

There are many varying guidelines as to who is an appropriate candidate for IPT. (5,6) Some centers demand adherence prior to IPT commencement. (6) Most guidelines cite the following as being required to be a suitable candidate for IPT:

1.Good adherence to recommended T1DM therapy and follow up
2.At least 4 tests of blood glucose levels per day
3.Competent at carbohydrate counting
4.Willing to communicate with diabetes team
5.Principal caregiver (parent or older adolescent) has no significant psychological or drug or alcohol issues
6.Principal caregiver is mature and responsible

- A **"good"** candidate was defined as a patient who in the consensus view of the IPT team satisfied at least 5 of the 6 most common criteria for IPT.

- A **"poor"** candidates was defined as satisfying 4 or less criteria.

Once our team had gained experience with IPT we specifically targeted and initiated IPT in many children traditionally considered "poor" candidates. The individualized strategy was developed in a multidisciplinary case meeting which included emotional and behavioral expertise.

Our prerequisites for commencing IPT were that
- the patient/family wanted to trial IPT and
- there was a consensus within the team that IPT would be safe.

"Poor" candidates received protracted education and more intensive post pump support. All patients had direct phone access to the paediatrician and diabetes educator at all times.

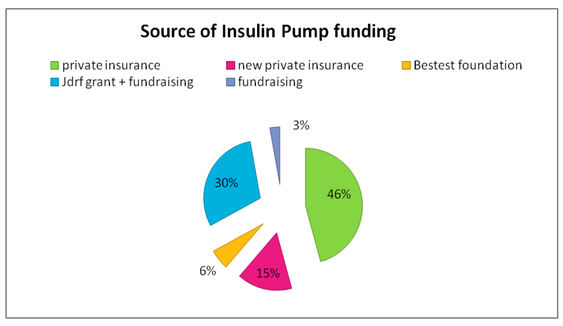
2. Uninsured patients

Because many families could not afford private health insurance, in 2007 we commenced a community fundraising campaign involving community service clubs, the local children's charity the Kate Buntine Children's Trust and the Shane Warne Foundation to assist families purchase an insulin pump. In 2008 the Australian Government introduced the "Type 1 Diabetes Insulin Pump Program" providing a subsidy for uninsured patients to purchase an insulin pump.

The uninsured patients were defined as those whose insulin pump was funded by means other than private health insurance.

Outcome was measured by comparing the average HbA1c of "good" and "poor" candidates and of insured and non-insured patients for the 12 months prior to IPT commencement with the average HbA1c at 3 months, over the first 12 months and over the second 12 months using student t test. Pre diagnosis HbA1c was omitted from analysis.

Episodes of severe hypoglycaemia (seizure or requiring glucagon rescue) and diabetic ketoacidosis (DKA) requiring admission to hospital were recorded.



Results

By the end of 2011, 56/67 (84%) current T1DM patients were managed with IPT and another 6/67 (9%) had trialed but ceased IPT.

Since 2007 we have initiated IPT in 67 patients and another 3 of our patients had IPT commenced elsewhere. Hence we have managed 70 patients with IPT, representing 131 patient years for the time period of this study.

Only 12 patients have not been offered IPT over the past 4 years. The reasons for not commencing IPT were unacceptable risk with extreme family chaos (4), low IQ (2), left the practice (3) and patient unwilling to trial IPT (3).

Six patients have ceased IPT - 4 voluntarily and 2 by our request because of unacceptable risk.

"Good" vs. "Poor" candidates

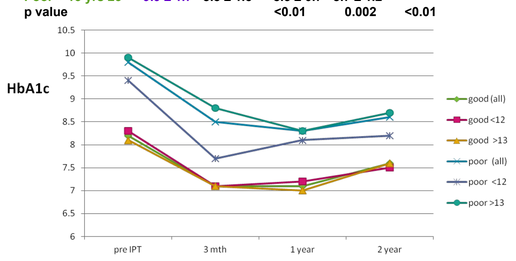
34/70 (51%) IPT were classified as "good" candidates. "Good" candidates (average age 12.6 ± 5.8 yrs) improved HbA1c from **8.2%** ± 0.71 to **7.1%** ± 0.52 ($p<0.001$) at 3 months, **7.1%** ± 0.74 ($p<0.0001$) over one year and **7.52** ± 0.97 ($p= 0.006$) over the second year.

36/70 children (49%) were classified as "poor" candidates (average age 14.7 ± 4.7yrs). Pre IPT HbA1c was **9.8%** ± 1.51 improving to **8.5%** ± 1.30 ($p<0.001$) at 3 months, **8.3%** ± 0.71 ($p<0.001$) over one year and **8.5%** ± 0.98 ($p<0.001$) over the second year.

"Good" candidates have significantly better HbA1c compared to "poor" candidates. ($p<0.001$). Only 2/34 "good" candidates has experienced severe hypoglycaemia over their first 2 years of IPT and no "good" candidate was admitted with DKA over those first 2 years.

6/36 "poor" candidates experienced severe hypoglycaemia ($p<0.001$) - a rate of 9.3 per 100 patient years. 6/36 "poor candidates" have been admitted to hospital with DKA in the first 2 years after commencement of IPT ($p<0.001$) though none more than once also representing a rate of 9.3 per 100 patient years. Those rates in "poor" candidates still compare favourably with other published series (7,8)

STATUS	n	pre IPT%	HbA1c 3/12	1 year	2 year
Total Good	34		8.2 ± 0.7	7.1 ± 0.7	7.1 ± 0.7 7.5 ± 1.0
p value				<0.001	<0.0001 0.006
Good <12 yrs	18		8.3 ± 0.5	7.1 ± 0.5	7.2 ± 0.6 7.5 ± 0.6
p value				0.002	0.001 0.002
Good > 13yrs	16	8.1 ± 0.9		7.1 ± 0.6	7.0 ± 0.8 7.6 ± 1.3
p value				0.002	< 0.001 0.002
Total Poor	36		9.8 ± 1.5	8.5 ± 1.3	8.3 ± 0.7 8.5 ± 1.0
p value				<0.001	<0.001 <0.001
Poor < 12 yrs	11	9.4 ± 1.0		7.7 ± 0.7	8.1 ± 0.7 8.2 ± 0.5
p value					<0.001 0.007 0.009
Poor > 13 yrs	25	9.9 ± 1.7		8.8 ± 1.5	8.3 ± 0.7 8.7 ± 1.2
p value					<0.01 0.002 <0.01



DKA and Hypoglycaemia

	n	DKA	Hypo
Good	34	0	2
Good <12	18	0	2
Good > 13	16	0	0
Ceased IPT	2		
Poor	36	6 ($p<0.001$)	6 ($p<0.001$)
Poor <12	11	3	4
Poor >13	25	3	2
Ceased IPT	4		
Rate/100 patient years		9.3	9.3
Overall Rate/100 patient years		4.6	6.1

Insured vs. Uninsured

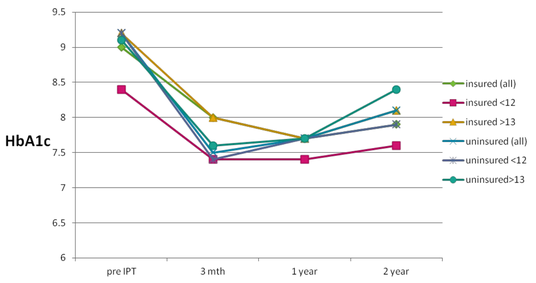
Of the 70 patients who commenced IPT, 43 utilised private health insurance (61%), including 11 (16%) who specifically purchased private insurance to obtain a pump. There have been 27 (39%) uninsured patients who have pumps funded by various grants and/or fundraising.

43 insured patients (average age 14.9 ± 5.5 yrs) significantly improved HbA1c from **9.0%** ± 1.5 to **8.0%** ± 1.4 at 3 months, **7.7%** ± 0.9 over the first year and **7.9%** ± 1.1 over the second year.

The 27 uninsured patients (average age 12.8 ± 4.5 yrs) significantly improved HbA1c from pre-pump average of **9.2%** ± 1.3 to 8.0% ± 0.83 at 3 months, **7.7%** ± 0.9 over the first year and **8.0%** ± 1.0 over the second year.

There was no significant difference between HbA1c of insured or uninsured patients managed with IPT over 2 years. ($p = 0.73$) and no significant difference between insured and uninsured patients in rates of DKA and severe hypoglycaemia.

STATUS	n	pre IPT%	HbA1c 3/12	1 year	2 year
Total Insured	43	9.0 ± 1.5	8.0 ± 1.4	7.7 ± 0.9	7.9 ± 1.1
p value			0.002	<0.0001	0.0006
Insured < 12 yrs	13	8.4 ± 0.9	7.4 ± 0.8	7.4 ± 0.8	7.6 ± 0.9
p value			0.002	0.002	0.01
Insured >13 yrs	30	9.0 ± 1.5	8.0 ± 1.4	7.7 ± 0.9	7.9 ± 1.1
p value			0.002	0.0002	0.003
Total Uninsured	27	9.2 ± 1.3	7.5 ± 0.8	7.7 ± 0.7	8.1 ± 1.0
p value			<0.001	<0.001	0.002
Uninsured < 12	16	9.2 ± 1.0	7.4 ± 0.6	7.7 ± 0.7	7.9 ± 0.5
p value			0.002	0.003	0.03
Uninsured > 13	11	9.1 ± 1.6	7.6 ± 1.0	7.7 ± 0.8	8.4 ± 1.2
p value			0.02	0.002	0.005



DKA and Hypoglycaemia

	n	DKA	Hypo
Insured	43	2	3
Insured <12	13	0	2
Insured > 13	30	2	1
Ceased IPT	4		
Uninsured	27	4 (p=0.06)	5 (p=0.06)
Uninsured <12	12	4	3
Uninsured >13	11	0	2
Ceased IPT	4		
Rate/100 patient years		8.1	10.2

Conclusion

- Insulin Pump Therapy, managed by a skilled rural multidisciplinary team using emotional and peer support, significantly improves glycaemic control in T1DM paediatric patients traditionally considered "poor" candidates that are most at risk of long term complications.

- The risk of DKA and severe hypoglycaemia is significantly more in poor candidates than "good" candidates but still at comparable rates to other tertiary centres.

- Selection criteria for IPT should not preclude traditionally "poor" candidates, provided the diabetes team provides extra support.

- IPT equally benefits the glycaemic control of both insured and uninsured patients given equal quality of diabetes team support.

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