3. PRE – BIOPSY MEDICATION - DESMOPRESSIN ACETATE

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GUIDELINES

No recommendations or suggestions can be made due to lack of evidence.

UNGRADED SUGGESTIONS FOR CLINICAL CARE

- There is a lack of evidence to support the benefit or harm of desmopressin acetate 0.3µg/kg administered intravenously over 30 minutes prior to renal biopsy. Units should continue their existing practice until a higher level of evidence is available. However, we suggest this is considered only for patients with Stage 3b chronic kidney disease and onwards.
- Careful attention to fluid balance should be paid if desmopressin is administered and excessive fluid intake should be discouraged for 6 to 8 hours after its administration.
- There is no evidence in any reports of a negative effect by using desmopressin in patients with cardiovascular disease. However, due to the hypothetical potential risk of thrombosis, desmopressin acetate should be avoided in patients with significant occlusive cardiovascular disease, including those with a vascular stent in situ.

IMPLEMENTATION AND AUDIT

1. All centres and proceduralists should maintain records of pre-biopsy medications and complications associated with all percutaneous native and allograft renal biopsies in a real time manner.
2. Outcomes and complications should be reviewed at regular audits and performance should be benchmarked to ensure safe practice.

BACKGROUND

There is a lack of evidence that uremic bleeding is due to deficiency or abnormality of factor VIII and von Willebrand Factor (vWF), and that the similar biological effects of desmopressin and cryoprecipitate on these haemostatic proteins led some investigators to postulate that desmopressin might be therapeutically effective. Desmopressin acetate is a synthetic analogue of antidiuretic hormone which is occasionally administered prior to percutaneous renal biopsy to reduce the risk of bleeding complications.(1, 2) It acts as a selective agonist of endothelial vasopressin-2 receptors, augmenting plasma levels of factor VIII and von Willebrand Factor (vWF).(3, 4) Plasminogen activator is simultaneously released, which enhances platelet adhesion to vessel walls.(5)

Although patients with acute and chronic kidney disease typically have normal circulating factor VIII and vWF levels, uraemia is associated with platelet dysfunction and increased bleeding risk. Various mechanisms have been proposed to explain this abnormality, including a dysfunctional interaction

between vWF and platelets, decreased platelet aggregation due to increased prostaglandin I2, and impaired platelet adhesion due to reduced levels of thromboxane A2 and ADP.(6)

Studies have demonstrated that infusion of desmopressin elicits a rapid but transient increase in the circulating levels of vWF and factor VIII, reaching a peak between 90 minutes to 2 hours after administration.(4) A single dose can be expected to increase the factor VIII level three to six-fold. It has been shown to normalise bleeding time in uraemia for up to 4-8 hours,(3, 7-9) presumably through its vasopressin-2 receptor agonist activity. The other effects of desmopressin include vasodilation, and an oxytocic effect at intranasal doses of 15-20µg. Desmopressin is typically administered at a dose of 0.3µg/kg intravenously, over a period of 20 to 30 minutes before a procedure.

Desmopressin increases free water reabsorption in renal collecting ducts, potentially leading to dilutional hyponatraemia if fluid restriction is not prescribed.(10) The reported rate of hyponatraemia is approximately 1 in 10,000. In rare cases, hyponatraemia may be severe, and lead to neurological sequelae.(11) Other adverse effects include hypotension, tachycardia, facial flushing, nausea and abdominal pain (common, 1-10%); water intoxication (uncommon, 0.1-1%); and dizziness (rare, <0.1%).(12) Tachyphylaxis has been reported in patients who have received multiple treatments.(13) It may be associated with increased thrombotic risk.(14)

SEARCH STRATEGY

Databases searched: The search was carried out in Medline (1946 – May 2017), The Cochrane Library (Central) and the Cochrane Kidney and Transplant Register of Studies, Embase (May2017). Text words for renal biopsy were combined with MeSH terms and text words for desmopressin, vasopressin and DDAVP. No language restrictions were placed on the search.
The search strategy is provided in the Appendices section.

Date of search/es: May 2017

WHAT IS THE EVIDENCE?

In a single-centre double-blind randomised controlled trial by Manno *et al.*(15) 162 patients undergoing percutaneous native renal biopsy were randomised to receive desmopressin 0.3µg/kg subcutaneously one hour before biopsy or placebo. Patients in this study had preserved renal function (serum creatinine ≤1.5mg/dL, and/or an estimated glomerular filtration rate ≥60mL/min/1.73m^2) and normal coagulation parameters. Indications for biopsy included haematuria or proteinuria (70%) or nephrotic syndrome (30%). Biopsies were ultrasound-guided and performed using a 16-gauge needle. The median number of passes was two. Blood pressure was <140/90mmHg and antiplatelet medications were ceased seven days prior to biopsy. Compared to placebo, administration of desmopressin reduced the incidence of perinephric haematoma located by ultrasound (relative risk 0.45, 95% confidence interval [CI] 0.24-0.85, P=0.01) and the size of the haematoma, if present (median 208 vs 380mm^2, P=0.006). Despite this, there was no difference in haemoglobin level or change, lumbar pain, or haemodynamic parameters. The absolute reduction in the incidence of haematoma was 16.8% and the number needed to treat was six. The desmopressin group had shorter hospital length of stay (mean 4.9±1.1 days vs 5.9±1.7 days, P=0.004). There were no significant differences in terms of post-biopsy haemoglobin level, glomerular filtration rate, or systolic or diastolic blood pressure. No serious adverse effects occurred, however the study was not powered to detect harm. Three patients experienced a transient increase in heart rate.

Radhakrishnan *et al.*(16) undertook a single-centre retrospective study of 43 children with acute or chronic renal disease who were undergoing percutaneous renal biopsy or central venous catheter insertion. Desmopressin was administered to 13 patients (30%) at a dose of 0.3µg/kg intravenously 30 to 60 minutes prior to the procedure. Biopsies accounted for 22 of the procedures and were performed using ultrasound guidance and an 18-gauge needle. Two cores were taken. A bleeding event was defined as gross haematuria, haematoma detected on imaging, a decrease in haemoglobin >15g/L, or the need for blood transfusion or pressure bandage application. Patients were categorised into three groups according to estimated glomerular filtration rate (eGFR <15ml/min/1.73m^2, 15-29ml/min/1.73m^2,

30-60ml/min/1.73m^2). No significant difference was found in the number of bleeding events between those who received and did not receive desmopressin either overall or in any eGFR subgroup. Of note, 0/5 patients with an eGFR <15ml/min/1.73m2 who received desmopressin had a bleeding event compared to 3/10 in the non-desmopressin group, however numbers were small, and statistical significance was not demonstrated (P=0.5). No adverse events relating to desmopressin administration were noted.

A study by Moledina *et al.*(17) included 159 adults hospitalised from two centres in the United States who underwent percutaneous renal biopsy to investigate acute kidney disease. Biopsies were performed using ultrasound or computed tomography guidance and either 16- or 18-gauge needles. The median number of passes was 3. Desmopressin (dose not reported) was administered to 124 patients within 4 hours of biopsy. A total of 7 of 12 patients (58%) requiring transfusion received desmopressin prior to biopsy, compared to 117 of 147 patients (80%) who did not require transfusion (p=0.09). Although not associated with transfusion on univariable analysis, after adjustment for blood urea nitrogen, administration of desmopressin was associated with a lower risk of transfusion (odds ratio 0.24; 95% CI 0.06 to 0,88).

In the setting of renal transplant, Tsai *et al.* (18) retrospectively studied complications following 269 allograft biopsies, all of whom received four units of desmopressin (1µg) intravenously 30 minutes prior to biopsy. Study participants had a systolic blood pressure <180mmHg and were not taking antiplatelet or anticoagulant medications. Biopsies were performed using ultrasound guidance and a 16- or 18-gauge needle. Two cores were recommended. Complications included gross haematuria in 2.2%, haematoma formation in 1.1%, fall in haemoglobin in 0.7%, and hydronephrosis in 0.4% of patients. Complication rates in this study were lower than those reported in non-desmopressin studies;(19) however, no non-desmopressin control arm was available in this study for direct comparison. There were no adverse events reported.

Side effects of desmopressin acetate use

A case study by Ensat *et al*.(20) a female patient had a facial tumour resected and an iliac bone graft with skin island created. Desmopressin 4µg was given five days post operation and venous congestion of the skin island was seen within one hour of desmopressin administration.

In a retrospective study involving 2804 simultaneous kidney-pancreas transplants (SKPT) from cadaveric donors, the effect of desmopressin use in the donor (desmopressin-Yes) or not (desmopressin-No) was assessed. There were 1287 SKPT patients (46%) who received a pancreas graft (PG) from a desmopressin-Yes donor. The incidence of PG thrombosis was 5.1% in recipients of desmopressin-Yes donor versus 3.5% in recipients of desmopressin-No donors, P = 0.04. The proportion of thrombosed PGs from desmopressin-Yes donors was 58% compared with 42% from desmopressin-No donors, P = 0.04.(21)

Levi *et al.*(22) conducted a meta-analysis of pharmacological strategies to decrease perioperative blood loss in patients undergoing cardiac surgery. Seventy-two trials (8409 patients) were included and 16 trials involved desmopressin and placebo. The use of desmopressin showed a small decrease in perioperative blood loss but was not associated with other clinical beneficial effects. However, the increased risk of thrombotic events associated with desmopressin use is of concern. In five of seven trials reporting the incidence of myocardial infarction, desmopressin was associated with an increased risk of myocardial infarction, odds ratio [OR] 2.4 (95% confidence interval: 1.02 – 5.60) versus placebo. There was no difference in the risk of mortality between the desmopressin group versus placebo, OR 1.02 [95%CI: 0.29 – 3.56]. There was a 21% decrease in receiving a blood transfusion for patients in the desmopressin group compared with placebo OR 0.79 [95%CI: 0.56 – 1.11; p = not significant].

SUMMARY OF THE EVIDENCE

There is insufficient evidence to support the benefit or harm of desmopressin use pre-renal biopsy (0.3µg/kg administered intravenously over 30 minutes) to reduce the risk of post-renal biopsy bleeding in adults with renal failure. The two published randomised trials were in children or in adults with

preserved renal function, which means their findings are not generalisable to the population of adult patients in Australia and New Zealand undergoing renal biopsy.

WHAT DO THE OTHER GUIDELINES SAY?

Kidney Disease Outcomes Quality Initiative: No recommendation.
UK Renal Association: No recommendation.
Canadian Society of Nephrology: No recommendation.
European Best Practice Guidelines: No recommendation.
International Guidelines: No recommendation.

SUGGESTIONS FOR FUTURE RESEARCH

Randomised controlled trials comparing desmopressin against placebo are required to inform clinical decision making. Such trials should include patients with varying degrees of acute and chronic renal impairment, and should consider both native and transplant biopsy settings. Renal centres currently using desmopressin pre-renal biopsy should conduct a prospective observational study accounting for all patient outcomes post desmopressin use. Outcomes to consider include bleeding complications, haematoma size, hospital stay, and complications of treatment with desmopressin.

CONFLICT OF INTEREST

Emily See, Paul Champion de Crespigny, Pamela Lopez-Vargas, Talia Gutman, Karine Manera, Solomon Menahem, John Saunders, David Voss, Jeffrey Wong and Rob MacGinley have no relevant financial affiliations that would cause a conflict of interest according to the conflict of interest statement set down by KHA-CARI.

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APPENDICES

Table 1. Characteristics of included studies

Study ID	N	Study Design	Setting	Participants	Intervention (experimental group)	Intervention (control group)	Primary outcomes
Manno et al (2011)(15)	162 patients [80 = intervention; 80 = control]	RCT	Single centre, Italy	Patients undergoing percutaneous renal biopsy of the native kidney	Desmopressin acetate 0.3µg/kg	Placebo	• Bleeding
Radhakrishnan et al (2014)(16)	254 procedures	Retrospective review	Single centre, Canada	Children with acute kidney injury or CKD undergoing renal biopsy or central line placement,	Desmopressin acetate (0.3 µg/kg of body weight) given 30 - 60 minutes prior to the procedure	No desmopressin acetate	• Bleeding complications
Tsai et al (2016)(18)	269 allograft biopsies	Retrospective study	Single centre, Taiwan	Transplant patients undergoing renal allograft biopsy.	Desmopressin 4 units infused over 30 minutes	No comparator	• Haematoma • Gross haematuria • Hydronephrosis • Haemoglobin decline
Ensat et al (2013)(20)	1	Case study	Austria	Female had facial tumour resection with free vascularized iliac bone graft with a skin island	4mcg desmopressin given 5 days post op due to diabetes insipidus.	N/A	• Thrombosis
Marques et al (2004)(21)	2804 simultaneous kidney-pancreas transplant	Retrospective study	Single centre, USA	Recipients of simultaneous kidney-pancreas transplant (SKPT) from cadaveric donors	Desmopressin acetate given to donor	No desmopressin acetate given to donor	• Thrombosis
Levi et al (1999)(22)	72 trials (8409 patients) [16 trials compared Desmopressin and placebo]	Meta-analysis	The Netherlands	Patients undergoing cardiac surgery	Pharmacological strategies to decrease perioperative blood loss (aprotinin, lysine analogues, desmopressin) Desmopressin dose used in all studies was 0.3 - 0.6 µg/kg	Placebo	• Mortality, • Transfusion, • Myocardial infarction, • Perioperative blood loss.
Moledina et al (2018)(17)	159 patients	Prospective observational study	Multicentre, USA	Patients with acute kidney disease undergoing renal biopsy	Ultrasound or computed tomography with 16 or 18 gauge needle	No comparator	• Blood transfusion

Table 2. Risk of bias- Randomised controlled studies - Cochrane quality appraisal tool

Study ID	Selection Bias		Performance Bias	Detection Bias		Outcome assessment	Reporting Bias		Quality
	Random sequence	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessors	Incomplete outcome data (Attrition Bias)	Assessed blindly	Selective reporting	Other risks of Bias / Comment	
Manno et al (2011)(15)	low	low	low	unclear	low	low	low	Small study (N = 160)	Moderate

Table 3. Risk of bias – meta-analysis (AMSTAR)

Study ID	Priori design provided	Duplication - selection, extraction	Comprehensive literature search	Grey literature inclusion	List of studies provided	Characteristics of studies	Scientific quality	Appropriate in conclusions	Methods appropriate	Publication bias	Conflict of interest	Quality
Levi et al (1999)(22)	no	yes	yes	yes	no	no	yes	yes	yes	no	can't answer	Moderate

Table 4. Risk of bias- Other studies

Study ID	N	Study type	Quality	Comments
Radhakrishnan et al (2014)(16)	254 procedures	Retrospective study	Very low	No quality appraisal tool available; small sample size
Tsai et al (2016)(18)	269 allograft biopsies	Retrospective study	Very low	No quality appraisal tool available; small sample size
Ensat et al (2013)(20)	1	Case study	Very low	No quality appraisal tool available; small sample size
Marques et al (2004)(21)	2804 simultaneous kidney-pancreas transplant	Retrospective study	Low	No quality appraisal tool available; risk of bias
Moledina et al (2018)(17)	159 patients	Prospective observational study	Low	No quality appraisal tool available; small sample size

Table 5. Bleeding outcomes

Study ID	N	Study type	Intervention	Control	Outcome	Results	Quality
Manno et al (2011)(15)	162 patients [80 = intervention; 80 = control]	RCT	Desmopressin acetate 0.3µg/kg	Placebo	Bleeding complications	• Desmopressin acetate significantly decreased the risk of post-biopsy bleeding 13.7% (11/80) versus 30.5% (25/82), relative risk 0.45 (95%CI: 0.24 - 0.85, P = 0.01)	Moderate
Radhakrishnan et al (2014)(16)	254 procedures (22 patients had a biopsy; 21 patients had a central line placement)	Retrospective review	Desmopressin acetate (0.3 µg/kg of body weight) given 30 - 60 minutes prior to the procedure	No desmopressin	Bleeding complications	• 4/22 (18%) patients who had a renal biopsy had a bleeding episode, but no significant bleed. • 61 events took place in 43 patients were associated with eGFR <60mL/min/1.73 m2 • 3/13 (23%) in those that received desmopressin versus 8/30 (27%) in those that did not, odds ratio (OR) 0.82 (95%CI: 0.2 - 3.8), P=1.0 • No significant side effects noticed secondary to desmopressin administration. • Two significant events requiring blood transfusion occurred in patients having a central venous catheter inserted, they did not receive desmopressin and had an eGFR < 15mL/min/1.73 m2. Patients had graft-versus-host disease and lymphoma respectively.	Very low
					Bleeding complications eGFR < 15 mL/min/1.73 m^2	• 0/5 (0%) in desmopressin acetate group versus 3/10 (30%) in non- desmopressin group, OR not applicable P=0.5	
					Bleeding complications eGFR 15 - 29 mL/min/1.73 m^2	• 2/7 (29%) in desmopressin acetate group versus 2/4 (50%) in non- desmopressin group, OR 0.40 (95%CI: 0.03 - 5.2) P= 0.57	
					Bleeding complications eGFR 30 - 60 mL/min/1.73 m^2	• 1/1 (100%) in desmopressin acetate group versus 3/16 (19%) in non- desmopressin group, OR not applicable P=0.23	
Tsai et al (2016)(18)	269 allograft biopsies	Retrospective study	Desmopressin 4 units infused over 30 minutes	No comparator	Haematoma	• 3 cases (1.1%), P = 0.2	Very low
					Gross Haematuria	• 6 cases, (2.2%), P = 0.1 • 2 (0.7%) patients needed blood transfusions, P = 0.3	
					Hydronephrosis	• 1 case (0.4%), P = 0.3	
					Haemoglobin decline	• 2 cases, (0.7%), P = 0.2	
Moledina et al (2018)(17)	159 patients	Prospective observational study	Ultrasound or computed tomography with 16 or 18 gauge needle	No comparator	Blood transfusion	• 7/12 patients (58%) requiring blood transfusion were given desmopressin within 4 hours of biopsy compared to 117/147 (80%) who did not require a blood transfusion, p = 0.09 • Upon on controlling for BUN, desmopressin was associated with a lower risk of blood transfusions OR 0.24, (95%CI: 0.06-0.88)	

Table 6. Thrombosis and other outcomes

Study ID	N	Study type	Intervention	Control	Outcome	Results	Quality
Ensat et al (2013)(20)	1	Case report	4mcg desmopressin given 5 days post-op for diabetes insipidus.	N/A	Thrombosis	• Skin island showed signs of venous congestion within one hour of desmopressin administration. • Thrombectomy performed and patient was treated with low molecular heparin and acetylsalicylic acid. Further healing was uneventful.	Very low
Marques et al (2004)(21)	2804 simultaneous kidney-pancreas transplant	Retrospective study	Desmopressin given to donor	No desmopressin given to donor	Thrombosis	• Baseline characteristics were similar between both groups • 1287 SKPT patients (46%) received a pancreas graft (PG) from a desmopressin donor. • Incidence of PG thrombosis in recipients of desmopressin donor was 5.1% compared with 3.5% in recipients of non-desmopressin donors, P=0.04 • 58% of thrombosed PGs came from desmopressin donors compared with 42% from non-desmopressin donors, P=0.04. **Conclusion:** there appears to be a relationship between donor treatment with desmopressin and PG thrombosis.	Low
Levi et al (1999)(22)	72 trials (8409 patients) [16 trials compared Desmopressin and placebo]	Meta-analysis	Pharmacological strategies to decrease perioperative blood loss (aprotinin, lysine analogues, desmopressin) Desmopressin dose used in all studies was 0.3 - 0.6 µg/kg	Placebo	Mortality Blood transfusion, Myocardial infarction, Perioperative blood loss	• Desmopressin resulted in small decrease in perioperative blood loss but not associated with a beneficial effect on other clinical outcomes. • Desmopressin (five of seven trials) was associated with an increased risk of perioperative myocardial infarction versus placebo OR 2.4 [95%CI: 1.02 - 5.60] • Desmopressin - mortality in the desmopressin group did not differ from the placebo OR 1.02 [95%CI: 0.29 - 3.56] (8 trials, 702 patients) • Data on rethoracotomy between desmopressin and placebo OR 0.67 [95%CI: 0.37 - 1.37] p=non-significant • Decrease in blood transfusion for desmopressin versus placebo OR 0.79 [95%CI: 0.56 - 1.11], p = not significant	Moderate

Search Strategies - DDAVP

Medline 1946 - 8May2017

#	Searches
1	kidney diseases/
2	exp Renal Replacement Therapy/
3	Renal Insufficiency/
4	exp Renal Insufficiency, Chronic/
5	Diabetic nephropathies/
6	exp hypertension, renal/
7	(kidney disease* or renal disease* or kidney failure or renal failure).tw.
8	(ESRF or ESKF or ESRD or ESKD).tw.
9	(CKF or CKD or CRF or CRD).tw.
10	(pre-dialysis or predialysis).tw.
11	exp acute kidney injury/
12	(acute kidney failure or acute renal failure).tw.
13	(acute kidney injur$ or acute renal injur$).tw.
14	(acute kidney insufficie$ or acute renal insufficie$).tw.
15	acute tubular necrosis.tw.
16	(ARI or AKI or ARF or AKF or ATN).tw.
17	or/1-16
18	biopsy/
19	renal biops$.tw.
20	kidney biops$.tw.
21	or/18-20
22	17 and 21
23	*vasopressins/ or *arginine vasopressin/ or *deamino arginine vasopressin/
24	Desmopressin.mp.
25	DDAVP.mp.
26	or/23-25
27	22 and 26

Embase 1974 – May 2017

#	Searches
1	kidney disease/
2	chronic kidney disease/
3	kidney failure/
4	chronic kidney failure/
5	mild renal impairment/
6	stage 1 kidney disease/
7	moderate renal impairment/
8	severe renal impairment/
9	end stage renal disease/
10	diabetic nephropathy/
11	kidney transplantation/
12	renovascular hypertension/
13	(kidney disease* or renal disease* or renal failure or kidney failure).tw.
14	(CKF or CKD or CRF or CRD).tw.
15	(ESRF or ESKF or ESRD or ESKD).tw.
16	(pre-dialysis or predialysis).tw.
17	((kidney or renal) adj (transplant* or graft* or allograft*)).tw.
18	acute kidney failure/
19	acute kidney tubule necrosis/
20	(acute kidney failure or acute renal failure).tw.
21	(acute kidney injur$ or acute renal injur$).tw.
22	(acute kidney insufficie$ or acute renal insufficie$).tw.
23	acute tubular necrosis.tw.
24	(ARI or AKI or ARF or AKF or ATN).tw.
25	or/1-24
26	renal biopsy.mp.
27	exp kidney biopsy/
28	renal biops$.tw.
29	kidney biops$.tw.
30	26 or 27 or 28 or 29
31	25 and 30
32	exp desmopressin/
33	desmopressin.mp.
34	DDAVP.mp.
35	or/32-34
36	31 and 35
37	limit 36 to human