

Keamanan, Efektivitas, dan Kemampooterapan Larutan Tumescent One-per-Mil Berkadar Epinefrin Satu per Satu Juta dan Lidokain 0,2% dalam Operasi Bedah Tangan dan Ekstremitas Atas Tanpa Turniket: Studi Eksperimental dan Uji Klinis = The Safety, Efficacy and Applicability of One-per-Mil Tumescent Solution Containing One per Million Epinephrine and 0.2% Lidocaine in Surgery for the Hand and Upper Extremity without Tourniquet: Experimental and Clinical Studies

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Abstrak

Rangkaian penelitian ini ditujukan untuk mengkaji alternatif operasi tanpa turniket melalui upaya untuk mengetahui efektivitas, keamanan, dan kemampooterapan larutan *tumescent one-per-mil*. Desain penelitian merupakan penelitian eksperimental, uji acak buta ganda dan seri kasus klinis penggunaan larutan *tumescent* yang mengandung epinefrin 1 : 1.000.000 dan lidokain 0,2% yang dilaksanakan di Fakultas Kedokteran Universitas Indonesia dan RS Cipto Mangunkusumo selama periode Juli 2013-Desember 2017. Penelitian pada *flap* inguinal tikus Sprague-Dawley dilakukan untuk mengetahui kejelasan lapangan operasi, peran vasokompresi hidrostatik, dan kesintasan *flap*. Uji klinis dilakukan pada subjek normal melalui suntikan pada pulpa jari untuk mengetahui masa tunda optimal melalui pengukuran SpO₂; serta mengenali peran vasokompresi hidrostatik. Terapan klinis operasi sadar penuh dikawal dengan uji klinis untuk mengetahui mula dan lama kerja lidokain. Kelompok seri kasus meliputi operasi tangan dan ekstremitas atas pada kelompok anak, operasi kontraktur pascaluka bakar, operasi yang melibatkan tulang dan sendi, operasi eksisi malformasi vaskular, rekonstruksi web dengan *flap*, serta operasi sadar penuh. Uji statistik dilakukan dengan metode Chi-square, Wilcoxon bertingkat, uji t-independen dan berpasangan, dan ANOVA. Tingkat kemaknaan ditetapkan sebagai $p < 0,05$.

Operasi pada *flap* inguinal tikus menghasilkan 63/63 lapangan operasi bebas perdarahan dengan 26/26 *flap* hidup walaupun diberi perlakuan iskemia sebelum disuntik. Tidak dijumpai perbedaan kesintasan *flap* antara teknik suntik acak dan teknik teratur. Walaupun kedua kelompok mengalami penurunan bermakna TcPO₂, rerata TcPO₂ pascaperlakuan iskemia kelompok *tumescent* lebih rendah daripada rerata kelompok kontrol. Hasil uji klinis menunjukkan rerata delta SpO₂ pada kelompok epinefrin lebih besar secara bermakna daripada kelompok salin normal. Epinefrin menunjukkan masa tunda optimal 13,9 (SB 5,38) menit. Mula kerja lidokain 5 (1-9) menit dengan lama kerja 186,8 (SD 44.02) menit. Seluruh operasi pada 77 subjek bedah tangan dapat dikerjakan tanpa konversi turniket. Operasi sadar penuh efektif pada 20 dari 24 kasus. Lapangan operasi bebas perdarahan dapat dicapai sebesar 38,7%, baik pada subjek dewasa maupun anak. Epinefrin bersama-sama dengan efek vasokompresi hidrostatik efektif dalam menghasilkan lapangan operasi bebas perdarahan pada tikus. Keberhasilan hidup 100% *flap* yang telah diberi perlakuan iskemia sebelumnya menunjukkan keamanan larutan *one-per-mil*. Nilai saturasi yang menurun namun masih dalam rentang normal menunjukkan tidak terjadinya efek iskemia pada jari. Hasil studi pada tikus maupun subjek normal menunjukkan bahwa epinefrin bersama-sama dengan efek vasokompresi hidrostatik

berperan dalam penurunan perfusi tanpa mengakibatkan iskemia. Masa tunda optimal efek hiperfusi selama 14 menit menjadi referensi yang relevan untuk mendukung praktik klinis masa tunggu sebelum insisi selama 7-10 menit. Selain efektif, termasuk dalam operasi sadar penuh yang berlangsung tanpa konversi turniket, hasil pengamatan teknik *tumescent one-per-mil* pada operasi kontraktur pascaluka bakar mematahkan paradigma bahwa operasi harus dilakukan dengan turniket. Larutan *one-per-mil* juga aman diterapkan pada operasi kasus pediatrik dengan tidak dijumpainya nekrosis *flap* maupun jari anak. Berdasarkan evaluasi luaran fungsi pada seri kasus operasi pada kontraktur luka bakar dan *spaghetti wrists*, teknik *tumescent one-per-mil* menunjukkan potensinya untuk dapat diterapkan pada kasus-kasus kompleks.

Simpulan: Larutan *tumescent one-per-mil* aman, efektif, dan mampu terap untuk menggantikan turniket dalam operasi bedah tangan dan ekstremitas atas. Walaupun menyebabkan hipoperfusi, larutan *one-per-mil* tidak menyebabkan iskemia dan kematian jari. Masa tunda optimal sebelum insisi 13,9 menit, dengan mula dan lama kerja anestesi lokal masing-masing adalah 5 dan 186,8 menit.

.....The study series were aimed to delineate hand and upper extremity surgery without tourniquet by studying the efficacy, safety, and applicability of the *one-per-mil* tumescent solution.

Studies were designed as experimental studies, randomized clinical trials and clinical case series on the use of solution containing 1 : 1,000,000 epinephrine and 0.2% lidocaine. All the studies were conducted at Faculty of Medicine Universitas Indonesia and Cipto Mangunkusumo Hospital during the periode of July 2013-December 2017. Groin flaps in Sprague-Dawley rats were elevated to study the operative field clarity, the role of hydrostatic vasocompressive effect and flap survivals. Clinical trials were performed on normal subject's fingers to know the optimal time delay by measuring SpO₂, while also to delineate the role of vasocompressive effect. The practice of fully awake hand surgery was guided by clinical study to reveal the onset and duration of anaesthetic action. Case series were including grouped surgeries for the hand and upper extremity in children, post burn hand contractures, bone and joint related problems, vascular malformation, web reconstruction using flaps, and fully awake surgeries. Statistical analysis were performed using Chi-square test, Wilcoxon sign rank test, independent and pair t-test, and ANOVA. Significance was set at $p < 0.05$.

Studies on animal revealed 63/63 bloodless operative fields and 26/26 flaps survived even after given ischemic insult before injection. The random pattern injection technique was not significantly different from systematic pattern technique. The epinephrine group showed significantly lower TcPO₂ than control group, although both experienced significant decrease of TcPO₂. The mean delta of SpO₂ of the epinephrine group was significantly higher than control group in the clinical study. Epinephrine showed optimal time delay 13.9 (SD 5.38) minutes. The average onset and duration of lidocaine actions were 5 (1-9) and 186.8 (SD 44.02) minutes respectively. Surgery on 77 subjects was successfully performed without tourniquet conversion. Fully awake surgery was effective in 20 out of 24 cases. Overall, bloodless operative field was achieved in 38.7%.

Epinephrine works together with hydrostatic vasocompressive effect in creating bloodless operative field in animal tissue. The safety was proven by the fact of 100% survival rate of flaps after surviving from ischemic insult. The decrease of SpO₂ which was still within normal range, is an evidence of non-ischemic fingers. Both experimental and clinical studies showed that epinephrine and hydrostatic vasocompressive effect are responsible to create hypoperfusion without causing ischemia. The 14 minutes optimal time delay is relevant to the clinical practice of 7-10 minutes waiting time before incision. Besides

its efficacy, the study outcome of one-per-mil tumescent technique to facilitate surgery on burn contracture breaks the old paradigm about surgery under tourniquet. The technique is also safe to be applied in paediatric patients as it showed no evidence of flap or finger necrosis. Based on the evaluation of functional outcome, one-per-mil tumescent technique is promising to be used in complicated surgeries.

In summary, one-per-mil tumescent solution is safe, effective and clinically applicable to substitute tourniquet in surgery for the hand and upper extremity. Although causing hypoperfusion, one-per-mil solution did not cause ischemia and subsequent finger necrosis. The optimal time delay is 13.9 minutes; the onset and duration of local anaesthesia is 5 and 186.8 minutes respectively.