Thermal Stability of 0.9% Sodium Chloride IV Fluid Exposed to Short- and Long-Term Extreme Conditions

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Background

- 0.9% sodium chloride IV fluid (normal saline) is critical in a clinical setting and may save lives [1].
- It is a cornerstone of intravenous solutions commonly used in the clinical setting (hospitals, clinics, recovery center and other) [2].
- Normal saline is an isotonic concentration of sodium chloride, which is best suited for parenteral replacement of chloride losses that exceed or equal the sodium loss [3,4].
- In the GCC region including Qatar, temperature value may rise over 50ºC, according to climate data from Civil Aviation Authority of Qatar [5].

Objectives

Data on thermal stability of normal saline, in out-of-hospital settings, are lacking. The aim of this study was to evaluate the effect of temperature on normal saline stability at constant temperature of 22, 50, or 70˚ C, and at cyclic temperature of 70˚ C for 8 hours and 22˚ C for 16 hours for a period up to 28 days.

Methods

- Normal saline provided in flexible plastic containers (Qatar Pharma, BA:1929013008, n=96) were stored at constant temperature of 22, 50, or 70˚ C, and at cyclic temperature of 70˚ C for 8 hours and 22˚ C for 16 hours for a period up to 28 days.
- The containers were sampled at 0, 12, 24, 48 and 72 hours and at 1, 2, 3, and 4 weeks in the short- and long-term study, respectively.
- A 1 mL of normal saline was withdrawn from each container and stored at 4˚ C until analysis. A 20 µL was diluted in 12 mL distilled water to be injected into ion exchange chromatography instrument (Metrohm, 850 Professional IEC) for the measurement of sodium and chloride levels.

Limitation

- Exclusion of relative humidity value and temperature over 70˚ C in this thermal stability study.
- Storage in the cabinet of ambulance vehicles during hot summer season in an arid country like Qatar is to be assessed in real-life conditions.

Recommendations

- Normal saline containers are stable up to 4 weeks under simulated constant and cyclic high temperatures.
- The flexible plastic container can withstand heat up to 70˚ C.
- The physical properties of normal saline (color and clarity) is not changed under this study thermal conditions.
- We aim to collaborate with Hamad Medical Corporation Ambulance Service in Qatar to study the thermal stability of normal saline in out-of-hospital settings.

Results

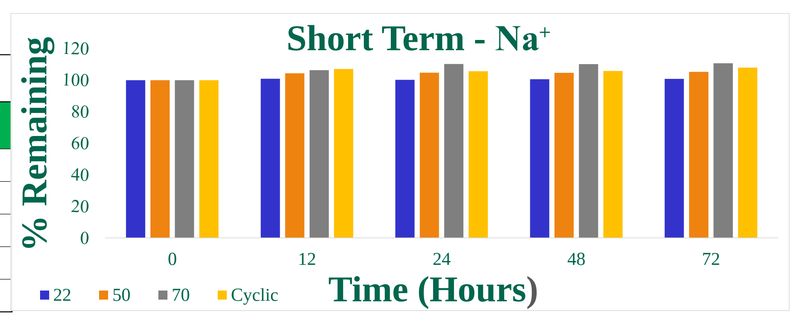
Fig. 1 Influence of temperature on bulging of normal saline container

- Discoloration or turbidity of normal saline fluid was not observed at any temperature or exposure period.
- The container slightly bulged at 50˚C and largely bulged at 70˚C & cyclic.
- The pH was 5.59±0.08 at 22˚C, 5.73±0.04 at 50˚C, 5.86±0.02 at 70˚C and 5.79±0.03 at cyclic.

Table 1. Remaining percentage of sodium and chloride (n=9) in short-term stability study

T (ºC)	Na^+- (% Remaining ± SD) Time (Hours)				
	0	12	24	48	72
22	100	100,86±0.76	100,2±0.93	100,6±0.55	100,81±0.74
50	100	104,35±1.50	104,73±1.87	104,66±0.76	105,28±0.26
70	100	106,34±0.79	110,24±0.85	110,15±1.55	110,68±0.76
Cyclic	100	107,13±1.60	105,67±1.13	105,76±1.56	107,9±0.75

T (ºC)	Cl^-- (% Remaining ± SD) Time (Hours)				
	0	12	24	48	72
22	100	99,29±0.74	99,04±0.58	99,49±0.74	99,41±0.44
50	100	101,34±1.80	100,42±1.72	100,09±0.71	101,07±0.75
70	100	100,09±1.39	101,66±1.33	102,11±1.71	102,00±0.72
Cyclic	100	100,48±1.62	99,79±1.81	100,02±1.61	100,86±0.90



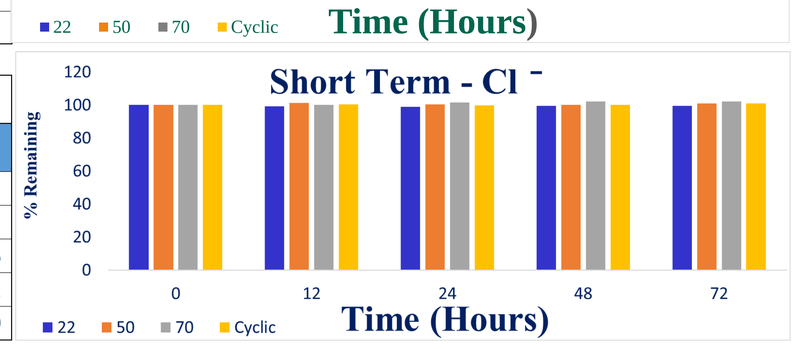
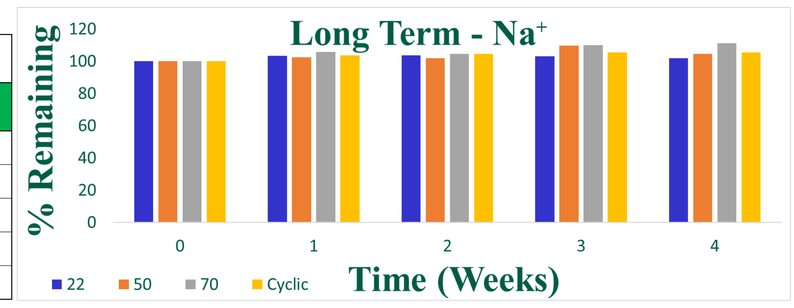
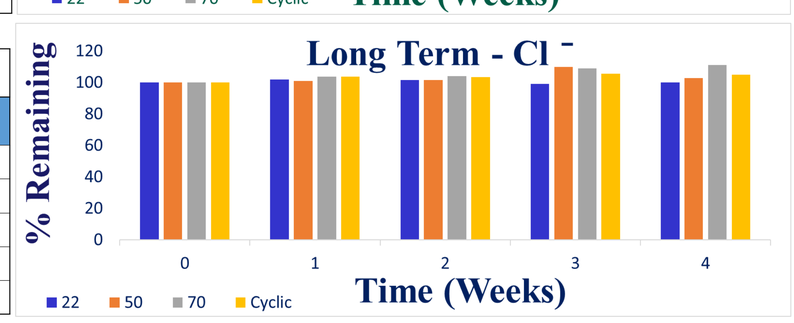


Table 2. Remaining percentage of sodium and chloride (n=9) in long-term stability study

T (ºC)	Na^+- (% Remaining± SD) Time (Weeks)				
	0	1	2	3	4
22	100	103,43±0.64	103,66±2.32	103,04±1.69	101,93±0.9
50	100	102,45±0.77	101,95±0.82	109,76±1.78	104,46±4.22
70	100	105,80±1.06	104,67±2.55	109,87±2.0	111,27±2.61
Cyclic	100	103,73±1.8	104,51±1.59	105,38±1.48	105,57±1.68

T (ºC)	Cl^-- (% Remaining ±SD) Time (Weeks)				
	0	1	2	3	4
22	100	101.87±1.10	101,56±1.67	99,05±0.94	100,03±0.76
50	100	100,79±1.02	101,55±1.28	109,87±1.28	102,85±1.98
70	100	103,66±0.80	104,01±2.38	108,78±2.38	110.95±1.63
Cyclic	100	103,68±1.37	103,35±1.14	105,52±0.82	104,99±1.58





- Remaining sodium and chloride levels ranged from 100.2±0.26% to 111.27±4.22% and from 99.04±0.76 to 110.95±2.62%, respectively.

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